

Opko Health, Inc.  
Form 10-Q  
August 08, 2008

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 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, 2008.

**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 000-27748

**OPKO Health, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

75-2402409  
(I.R.S. Employer Identification No.)

4400 Biscayne Blvd., Suite 1180  
Miami, FL 33137  
(Address of Principal Executive Offices)

(305) 575-4138  
(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 o NO x

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

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

YES ☐ NO ☒

As of July 30, 2008, the registrant had 184,651,391 shares of common stock, par value \$0.01, outstanding.

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## PART I. FINANCIAL INFORMATION

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains “forward-looking statements,” as that term is defined under the Private Securities Reform Litigation 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 elsewhere in this Quarterly Report on Form 10-Q, in “Item 1A-Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2007, and such factors as are 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.
- We will require substantial additional funding during the first half of 2009, which may not be available to us on acceptable terms, or at all.
- We are highly dependent on the success of our lead product candidate, bevasiranib, and we cannot give any assurance that it will receive regulatory approval or be successfully commercialized.
- The results of previous clinical trials may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non-United States regulatory authorities.
- 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.
- We may be unable to resolve issues relating to an FDA warning letter in a timely manner.
- 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.
- As we 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 rely on third parties to manufacture and supply our pharmaceutical product candidates, and would need to meet various standards necessary to satisfy FDA regulations 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 may be 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 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.
- 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.
- Acquisitions may disrupt our business, distract our management and may not proceed as planned; and we may encounter difficulties in integrating acquired businesses.
- Non-United States governments often impose strict price controls, which may adversely affect our future profitability.
- Our business may become subject to economic, political, regulatory and other risks associated with international operations.

· The market price of our common stock may fluctuate significantly.

- Directors, executive officers, principal stockholders and affiliated entities own a 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 other 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 American Stock Exchange, which could cause our stock price to fall and decrease the liquidity of our common stock.
  - Future issuances of common stock and hedging activities may depress the trading price of our common stock.
- Provisions in our charter documents and Delaware law could discourage an acquisition of us by a third party, even if the acquisition would be favorable to you.

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

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)

	June 30, 2008	December 31, 2007
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 5,484	\$ 23,373
Accounts receivable, net	1,131	1,689
Inventory	3,230	2,214
Prepaid expenses and other current assets	1,713	1,936
Total current assets	11,558	29,212
Property and equipment, net	598	410
Intangible assets, net	8,594	9,931
Other assets	162	15
Total assets	\$ 20,912	\$ 39,568
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 2,635	\$ 3,319
Accrued expenses	4,567	3,858
Capital lease obligations and current portion of note payable, net unamortized discount of \$0 and \$8, respectively	70	2,546
Total current liabilities	7,272	9,723
Long-term liabilities and capital lease obligations	1,143	1,372
Line of credit with related party, net unamortized discount of \$214 and \$311, respectively	11,786	11,689
Total liabilities	20,201	22,784
Commitments and contingencies		
Shareholders' equity		
Series A Preferred stock - \$0.01 par value, 4,000,000 shares authorized; 876,767 and 954,799 shares issued and outstanding (liquidation value of \$2,302 and \$2,387) at June 30, 2008 and December 31, 2007, respectively	9	10
Series C Preferred Stock - \$0.01 par value, 500,000 shares authorized; no shares issued or outstanding	-	-
Common Stock - \$0.01 par value, 500,000,000 shares authorized; 184,529,281 and 178,344,608 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	1,845	1,783
Additional paid-in-capital	290,008	284,273
Accumulated deficit	(291,151)	(269,282)
Total shareholders' equity	711	16,784
Total liabilities and shareholders' equity	\$ 20,912	\$ 39,568

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

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

	For the three months ended June 30,		For the six months ended June 30,	
	2008	2007	2008	2007
Revenue	\$ 879	\$ -	\$ 3,703	\$ -
Cost of goods sold	1,025	-	4,355	-
Gross margin (deficit)	(146)	-	(652)	-
Operating expenses:				
Selling, general and administrative	3,218	5,339	8,562	5,428
Research and development	5,479	5,434	9,835	11,507
Write-off of acquired in-process research and development	1,398	-	1,398	243,761
Other operating expenses, principally amortization of intangible assets	428	-	854	-
Total operating expenses	10,523	10,773	20,649	260,696
Operating loss	(10,669)	(10,773)	(21,301)	(260,696)
Other (expense) income, net	(249)	(165)	(518)	(178)
Loss before income taxes and loss from OTI	(10,918)	(10,938)	(21,819)	(260,874)
Income taxes	39	-	60	-
Net loss before loss from OTI	(10,879)	(10,938)	(21,759)	(260,874)
Loss from OTI	-	(35)	-	(35)
Net loss	(10,879)	(10,973)	(21,759)	(260,909)
Preferred stock dividend	(55)	(113)	(110)	(122)
Net loss attributable to common shareholders	\$ (10,934)	\$ (11,086)	\$ (21,869)	\$ (261,031)
Loss per share, basic and diluted	\$ (0.06)	\$ (0.09)	\$ (0.12)	\$ (2.86)
Weighted average number of shares outstanding - basic and diluted	183,707,302	117,871,000	182,139,632	91,399,000

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



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

	For the six months ended June 30,	
	2008	2007
Cash flows from operating activities		
Net loss	\$ (21,759)	\$ (260,909)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	906	8
Write-off of acquired in-process research and development	1,398	243,761
Accretion of debt discount related to notes payable	109	69
Loss from investment in OTI	-	35
Share based compensation - employees and non-employees	4,209	11,947
Changes in:		
Accounts receivable, net	558	-
Inventory	(1,015)	-
Prepaid expenses and other current assets	222	86
Other assets	(148)	(7)
Accounts payable	(812)	(577)
Accrued expenses and long-term liabilities	882	(744)
Net cash used in operating activities	(15,450)	(6,331)
Cash flows from investing activities		
Acquisition of OTI	-	(5,000)
Acquisition of businesses, net of cash	48	1,135
Capital expenditures	(239)	(21)
Net cash used in investing activities	(191)	(3,886)
Cash flows from financing activities:		
Issuance of common stock	-	16,284
Insurance financing	190	-
Proceeds from the exercise of stock options and warrants	269	-
Repayments of notes payable and capital lease obligations	(2,707)	-
Net cash (used in) provided by financing activities	(2,248)	16,284
Net (decrease) increase in cash and cash equivalents	(17,889)	6,067
Cash and cash equivalents at beginning of period	23,373	116
Cash and cash equivalents at end of period	\$ 5,484	\$ 6,183
SUPPLEMENTAL INFORMATION		
Interest paid	\$ 98	\$ 163
NON-CASH INVESTING AND FINANCING ACTIVITIES		
Issuance of Capital Stock to acquire Vidus and Acuity in 2008 and 2007	\$ 1,319	\$ 243,623

*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, imaging and diagnostic systems, and instruments for the treatment, diagnosis, and management of ophthalmic disorders. 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 are a Delaware corporation, headquartered in Miami, Florida, with instrumentation operations in Toronto, Ontario (Canada) and clinical operations in Morristown, New Jersey.

The three and six month periods ended June 30, 2007 includes our minority interest results for OTI, which we acquired on April 13, 2007. We acquired the remaining stock of OTI on November 28, 2007 and as a result, the 2008 period reflects the full operations of OTI.

**NOTE 2 LIQUIDITY**

We have not generated positive cash flow from operations since our inception, and 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 do not have the cash and cash equivalents on hand at June 30, 2008 sufficient to meet our anticipated cash requirements for operations and debt service for the next 12 months, and we will require additional funding during the first half of 2009. If we accelerate our product development programs or initiate additional clinical trials, we will need additional funds earlier. Our future cash requirements will depend on a number of factors, including 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, and take other actions designed to reduce our cost of operations, all of which may not significantly extend the period of time that we will be able to continue operations without raising additional funding.

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, the issuance of debt or equity securities, debt financing and revenues from future product sales, if any. To the extent we raise additional capital by issuing equity securities or obtaining borrowings convertible into equity, ownership dilution to existing stockholders will result and future investors may be granted rights superior to those of existing stockholders. Other than as set forth in Note 10, we do not currently have any commitments for future external funding and there can be no assurance that additional capital will be available to us on acceptable terms, or at all.

**NOTE 3 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 six months ended June 30, 2008 are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2008 or for future periods. The interim 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, 2007.

*Principles of consolidation:* The accompanying unaudited condensed consolidated financial statements include the accounts of OPKO Health, Inc. and our wholly-owned subsidiaries. All significant inter-company 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 income or loss.* Our comprehensive loss has no components other than net loss for all periods presented.

*Reclassifications:* Certain prior period amounts have been reclassified to conform to the current year's presentation.

*Recent accounting pronouncements:*

*Fair Value.* We have adopted the provisions of Statement of Financials Standards No. 157 *Fair Value Measurements*, or SFAS 157 as of January 1, 2008, for financial assets and liabilities. Although the adoption of SFAS 157 did not materially impact our financial condition, results of operations, or cash flows, we are now required to provide additional disclosures as part of our financial statements.

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, 2008, we held money market funds that 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. If we determine that any future valuation adjustment was other-than-temporary, we would record a charge to earnings 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 at June 30, 2008					
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total	
<b>Assets:</b>					
Money market funds	\$ 4,896	\$ —	\$ —	\$	4,896
<b>Total</b>	<b>\$ 4,896</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$</b>	<b>4,896</b>

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 on an instrument-by-instrument basis.

In June 2007, the Emerging Issues Task Force (Task Force) of the FASB reached a consensus on Issue No. 07-3 (“EITF 07-3”), Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities. Under EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for research and development activities should be deferred and capitalized. Such payments should be recognized as an expense as the goods are delivered or the related services are performed, not when the advance payment is made. If a company does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. We have adopted EITF 07-3 as of January 1, 2008. The adoption of EITF 07-3 did not have a material effect on our consolidated results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations. SFAS 141R will require, among other things, the expensing of direct transaction costs, including deal costs and restructuring costs as incurred, acquired in-process research and development assets to be capitalized, certain contingent assets and liabilities to be recognized at fair value and earn-out arrangements, including contingent consideration, may be required to be measured at fair value until settled, with changes in fair value 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. SFAS No. 141R 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” (“SFAS No. 160”). SFAS No. 160 requires minority interests to be recharacterized as noncontrolling interests and reported as a component of equity. In addition, SFAS No. 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 No. 160 is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited. We do not expect a material impact on our financial statements from the adoption of this standard.

#### **NOTE 4 ACQUISITION**

On May 6, 2008, we completed the acquisition of Vidus Ocular, Inc. (“Vidus”), a privately-held company that is developing Aquashunt™, a shunt to be used in the treatment of glaucoma. 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 its common stock. A portion of the Closing Shares and the Milestone Shares will remain in escrow for a period of one year to satisfy indemnification claims.

We have accounted for this acquisition as an asset acquisition. We valued our common stock issued to Vidus’ stockholders at the average closing price on the date of the acquisition and the two days prior to the transaction, or \$1.65 per share. In addition, we valued the options to acquire our common stock that were issued to the founders of Vidus using the black-scholes pricing model and recorded the value of those options as part of the purchase price of

Vidus, or \$1.17 per common stock option. All other contingent consideration will be valued and added to the purchase price if the milestones occur.

The table below reflects the estimated fair value of the net assets acquired at the date of acquisition:

(in thousands)

Current assets (cash of \$48)	\$ 48
In-process research and development	1,398
Accounts payable and accrued expenses	(127)
Total purchase price	\$ 1,319

The portion of the purchase price allocated to in-process research and development of \$1.4 million was immediately expensed. The purchase consideration issued and the purchase price allocations are preliminary pending completion and review of related valuation procedures. As a result the amounts above are subject to change.

The following tables include the pro forma results for the three and six month periods ended June 30, 2008 and June 30, 2007, respectively, of the combined companies as though the acquisition of Vidus had been completed as of the beginning of each period, respectively. The operating results of Vidus after May 6, 2008 have been included in our operating results in the accompanying condensed consolidated financial statements.

(in thousands, except per share amounts)	For the three months ended June 30, 2008	For the three months ended June 30, 2007
Revenue	\$ 879	\$ -
Net loss attributable to common shareholders	\$ (11,189)	\$ (11,348)
Basic and diluted loss per share	\$ (0.06)	\$ (0.10)

(in thousands, except per share amounts)	For the six months ended June 30, 2008	For the six months ended June 30, 2007
Revenue	\$ 3,703	\$ -
Net loss attributable to common shareholders	\$ (22,415)	\$ (261,412)
Basic and diluted loss per share	\$ (0.12)	\$ (2.84)



**NOTE 5 LOSS PER SHARE**

Basic loss per share is computed by dividing our net loss attributable to common shareholders by the weighted average number of shares outstanding during the period. When the effects are not anti-dilutive, 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 29,515,241 and 43,104,781 common stock equivalents have been excluded from the calculation of net loss per share in the three months ended June 30, 2008 and June 30, 2007, respectively, and a total of 26,856,410 and 24,710,590 common stock equivalents have been excluded from the calculation of net loss per share in the six months ended June 30, 2008 and June 30, 2007, respectively, because their inclusion would be anti-dilutive.

**NOTE 6 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS**

(in thousands)	June 30, 2008	December 31, 2007
<b>Accounts receivable, net:</b>		
Accounts receivable	\$ 1,596	\$ 2,154
Less allowance for doubtful accounts	(465)	(465)
	\$ 1,131	\$ 1,689
<b>Inventories:</b>		
Raw materials (components)	\$ 2,493	\$ 1,913
Finished products	737	301
	\$ 3,230	\$ 2,214
<b>Intangible assets, net:</b>		
Technology	\$ 4,597	\$ 4,597
Customer relationships	2,978	2,978
Covenants not to compete	317	317
Tradename	195	195
Other	262	262
Less amortization	(1,004)	(150)
Goodwill	1,249	1,732
	\$ 8,594	\$ 9,931

On November 28, 2007, we acquired Ophthalmic Technologies, Inc. (“OTI”), for approximately \$11.7 million. We allocated the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values under the provisions of SFAS No. 141, Business Combinations (SFAS No. 141). We believe the estimated fair values assigned to the OTI 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 No. 141, which is up to one year from the acquisition date, if additional information becomes available that would require changes to our estimates.

**NOTE 7 TERM LOAN**

On January 11, 2008, we repaid, in full, all outstanding amounts and terminated all of our commitments under our \$4.0 million term loan with Horizon Financial Funding Company, LLC, which was being repaid monthly since August 2007 and was to be paid in full by August 2008. During the first quarter of 2008, the total amount we repaid in satisfaction of our obligations under the term loan was \$2.4 million.

**NOTE 8 COMMITMENTS AND CONTINGENCIES**

On May 7, 2007, Ophthalmic Imaging Systems filed a lawsuit against one of our former employees for breach of fiduciary duty, intentional interference with contract and intentional interference with prospective economic advantage. The Company agreed to indemnify the former employee, who has since been terminated. On April 14, 2008, the plaintiff was granted leave to file a Second Amended Complaint to add claims for tortious interference with prospective business advantage and aiding and abetting against the Company and The Frost Group, LLC, (a related party) seeking in excess of \$7 million in damages. Discovery in this matter is ongoing. The Company believes this action is without merit and is vigorously defending itself against the claims. It is too early to assess the probability of a favorable or unfavorable outcome, or the loss or range of loss or indemnification obligation, if any, and therefore, no amounts have been accrued relating to this action.

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 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. The total potential obligation for this former employee is approximately \$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 \$0.2 million in accrued expenses as of June 30, 2008 based on the estimated fair value of these put options.

On March 25, 2008, OTI received a warning letter in connection with a FDA inspection of OTI's Toronto facility in July and August of 2007. The warning letter cited several deficiencies in OTI's quality, record keeping, and reporting systems relating to certain of OTI's products, including the OTI Scan 1000, OTI Scan 2000, and OTI OCT/SLO combination imaging system. Based upon the observations noted in the warning letter, OTI is not currently in compliance with cGMP. The FDA indicated that it issued an Import Alert and may refuse admission of these products into the United States. As a result, we are not currently permitted to sell these devices in the United States, and our pending 510(k) pre-market notification submission for the OCT/SLO combination imaging system will be delayed until the violations have been corrected. We have determined that a limited number of the OCT/SLO imaging systems were shipped to customers in the United States prior to our receipt of the warning letter and prior to clearance of a 510(k) submission. We have contacted our customers to recover the limited number of OCT/SLO products at issue and are in the process of reimbursing customers for such products. We are also evaluating the amount of any reimbursement made by federal health care programs for procedures utilizing the OCT/SLO device.

We are cooperating fully with the FDA, and will continue to work with the agency on all of the above-referenced issues. Upon receipt of the warning letter, we immediately began to take corrective action to address the FDA's concerns and to assure the quality of OTI's products. We are committed to providing high quality products to our customers, and we plan to meet this commitment by working diligently to remedy these deficiencies and to implement updated and improved quality systems and concepts throughout the OTI organization.

In connection with our acquisition of Vidus, we are required to release from escrow, or issue, up to 902,270 shares our common stock upon the achievement of certain milestones. Refer to Note 4.

## **NOTE 9 RELATED PARTY TRANSACTIONS**

Our principal corporate office is located at 4400 Biscayne Blvd, Suite 1180, Miami, Florida. We lease this space from Frost Real Estate Holdings, LLC, an entity which is controlled by Dr. Phillip Frost, our Chairman of the Board and Chief Executive Officer. Pursuant to the lease agreement with Frost Real Estate Holdings (the "Lease"), we lease approximately 8,300 square feet, which encompasses space for our corporate offices, administrative services, preclinical research and development, project management and pharmacology. The Lease is for a five-year term and currently requires annual rent of approximately \$221,000, which amount increases by approximately 4.5% per year.

Effective as of January 1, 2008, we began leasing an additional 1,100 square feet of general office and laboratory space on a ground floor annex of our corporate office building. Pursuant to an addendum to the Lease, we will be required to pay annual rent of \$19,872 per year for the annex space, which amount will be subject to a 4.5% increase each year, and shall otherwise be governed by the terms of the Lease.

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, 2008, we reimbursed Dr. Frost approximately \$44,000 and \$86,000, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

During the three and six months ended June 30, 2008, we reimbursed SafeStitch Medical, Inc. ("SafeStitch") approximately \$37,000, for time SafeStitch's personnel spent assisting us with the implementation of certain quality and control standard operating procedures at our manufacturing facility in Toronto, Ontario. Jane Hsiao, our Vice Chairman and Chief Technical Officer, serves as chairman of the board of directors for SafeStitch; and Steven Rubin, our Executive Vice President-Administration, and Richard Pfenniger, each of whom are members of our board of directors also serve on the board of directors of SafeStitch.

We have a fully utilized \$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. Phillip 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 10% annual rate, which is due July 11, 2009. The line of credit is collateralized by all of our personal property except our intellectual property.

#### **NOTE 10 SUBSEQUENT EVENT**

Pursuant to a Stock Purchase Agreement, dated as of August 8, 2008, a group of investors, which included members of The Frost Group, LLC, a private investment group controlled by Dr. Phillip Frost, M.D., Chairman and CEO of the Company, have agreed to make a \$15 million investment in the Company. Under the terms of the investment, the Company will issue to investors 13,513,514 shares of the Company's common stock, par value \$.01 (the "Shares"), at \$1.11 per share, representing an approximately 40% discount to the five-day average closing price of the common stock on the American Stock Exchange (the "Investment"). The Closing of the Investment and the issuance and delivery of the Shares will occur approximately twenty (20) days after the mailing of an Information Statement to stockholders, which we currently anticipate will be on or around September 10, 2008.

The Shares issued in the Investment will be restricted securities, subject to a two year lockup, and no registration rights have been granted. The issuance of the Shares will be exempt from the registration requirements under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof, because the transaction does not involve a public offering.

In addition to Frost Gamma Investments Trust, of which Phillip Frost, M.D., is the sole trustee, The Frost Group also includes Dr. Jane Hsiao, Vice Chairman and Chief Technical Officer of OPKO, Dr. Rao Uppaluri, the Company's Chief Financial Officer, and Mr. Steven D. Rubin, the Company's Executive Vice President-Administration.

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

### **OVERVIEW**

*You should read this discussion together with the Financial Statements, related Notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2007 (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 I, Item 1A of our Form 10-K. 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 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, particularly bevasiranib, continue our other research and development activities, 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, 2008, we had an accumulated deficit of \$291.2 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 continued clinical development of bevasiranib and the research and development activities relating to our technology and other product candidates. 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 during the first half of 2009 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, 2008 AND 2007**

The three month period ended June 30, 2007 includes our minority interest results for OTI, which we acquired on April 13, 2007. We acquired the remaining stock of OTI on November 28, 2007 and as a result, the 2008 period reflects the full operations of OTI.

**Revenue.** Revenue for the three months ended June 30, 2008 was \$0.9 million. All revenue was generated from sales of OTI's ophthalmic instrumentation products. Until the acquisition of OTI on November 28, 2007, we did not generate any revenue. There were limited sales of OTI's OCT/SLO product internationally and no sales of the OCT/SLO product in the U.S. during the quarter ended June 30, 2008. Commencement of sales for this product in the U.S. will not occur until we have received clearance of the premarket notification 510(k) for the device by the U.S. Food and Drug Administration ("FDA") and have satisfied the FDA with our response to the March 25, 2008 warning letter received by OTI. We expect revenue to increase during the second half of 2008 and first half of 2009 as we

complete the transition of manufacturing our OCT/SLO product in-house and begin selling the OCT/SLO product in the U.S. following receipt of clearance of the premarket notification 510(k) for the device by the FDA.

*Gross margin (deficit).* Gross deficit for the three months ended June 30, 2008 was (\$0.1) million and was entirely related to our ophthalmic instrumentation product sales. The gross deficit was negatively impacted by manufacturing costs associated with the introduction of our new OCT/SLO model internationally. In addition, gross deficit was impacted as we incurred approximately \$0.4 million to bring manufacturing of our OCT/SLO product in-house, including excess capacity costs.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the three months ended June 30, 2008 was \$3.2 million compared to \$5.3 million of expense for the comparable period of 2007. Selling, general and administrative expense primarily related to personnel costs, including stock-based compensation of \$0.9 million and \$2.6 million, for the three months ended June 30, 2008 and June 30, 2007, respectively, and professional fees. The 2007 period primarily reflects personnel costs including approximately \$2.6 million of expense related to stock-based compensation and professional fees. As we prepare to sell OTI's OCT/SLO product in the U.S., we anticipate sales and marketing expenses will increase in the later part of 2008 and thereafter.

*Research and Development Expense.* Research and development expense during the three months ended June 30, 2008 was \$5.5 million compared to \$5.4 million for the comparable period of 2007. The expense during the three months ended June 30, 2008 primarily reflects the cost of our ongoing Phase III clinical trial for bevasiranib, including costs of clinical trial site and monitoring expenses, clinical supplies, personnel costs and outside professional fees. Also included in personnel costs for the 2008 three-month period was \$0.6 million of stock-based compensation expense. Research and development expense for the 2007 three-month period primarily relates to stock based compensation expense of \$3.3 million, of which \$2.0 million was reversed in the third quarter of 2007 as a result of the termination of a consulting agreement. Under SFAS 123R, when a stock based compensation award is forfeited prior to vesting, all compensation expense recorded in previous periods is reversed in the period of forfeiture.

*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, 2007.

*Other operating expenses.* Other operating expenses primarily include amortization of intangible assets acquired from OTI on November 28, 2007. We did not record any amortization expense during the quarter ended June 30, 2007.

*Other Income and Expenses.* Other expense was \$0.2 million, net of \$0.1 million of interest income for the second quarter of 2008 compared to \$0.2 million of other expense for the 2007 period, net of \$0.1 million of other income. 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.

*Income taxes.* The income tax benefit for the three months ended June 30, 2008 reflects our estimated 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. We did not have similar refundable credits during the three months ended June 30, 2007.

#### **FOR THE SIX MONTHS ENDED JUNE 30, 2008 AND 2007**

The six month period ended June 30, 2008 includes our operations, as well as the operations of OTI, which we acquired on November 28, 2007. The six months ended June 30, 2007 include our results for the full period and the results of operations from Acuity Pharmaceuticals, Inc., or Acuity, subsequent to our acquisition on March 27, 2007.

*Revenue.* Revenue for the six months ended June 30, 2008 was \$3.7 million. All revenue was generated from sales of OTI's ophthalmic instrumentation products. Until the acquisition of OTI, we did not generate any revenue. During 2008, the majority of our revenue has been from international sales. There were no OCT/SLO product sales in the U.S. during the first six months of 2008. Commencement of sales for this product in the U.S. will not occur until we have received clearance of the premarket notification 510(k) for the device by the FDA and have satisfied the FDA with our response to the March 25, 2008 warning letter received by OTI. We anticipate revenue will increase during the remainder of 2008 and first half of 2009 as we move production of components for the OCT/SLO in-house and



begin selling the OCT/SLO product in the U.S. once we receive clearance of the premarket notification 510(k) for the device by the FDA.

*Gross margin (deficit).* Gross deficit for the six months ended June 30, 2008 was (\$0.7) million and was entirely related to our ophthalmic instrumentation product sales. The gross deficit was negatively impacted by manufacturing costs associated with the introduction of our new OCT/SLO model internationally. In addition, during the first six months of 2008, gross deficit was impacted as we incurred approximately \$0.9 million to bring manufacturing of our OCT/SLO product in-house, including costs associated with production development and excess capacity costs. We anticipate that our margin will improve as we begin manufacturing more components in-house and as we begin selling the OCT / SLO product in the U.S.

*Selling, General and Administrative Expense.* Selling, general and administrative expense for the six months ended June 30, 2008 was \$8.6 million compared to \$5.4 million of expense for the comparable period of 2007. Selling, general and administrative expense for the six months ended June 30, 2008 primarily related to personnel costs, including stock-based compensation of \$2.9 million and professional fees. In addition, as a result of our acquisition of OTI on November 28, 2007, our selling expenses reflect a full six months of post acquisition activity for OTI. As we prepare to sell OTI's OCT/SLO product in the U.S., we anticipate these expenses will increase in the later part of 2008 and thereafter. We acquired Acuity on March 27, 2007 and we had limited operations prior to that, resulting in limited operating expenses during a portion of the 2007 period. The 2007 period includes approximately \$2.7 million of expense related to stock-based compensation and professional fees.

*Research and Development Expense.* Research and development expense during the six months ended June 30, 2008 was \$9.8 million compared to \$11.5 million for the comparable period of 2007. The 2008 period expense primarily reflects the cost of our ongoing Phase III clinical trial for bevasiranib, including costs of clinical trial sites and monitoring expenses, clinical supplies, personnel costs and outside professional fees. Also included in personnel costs for the 2008 six month period was \$1.3 million in stock based compensation expense. Research and development expense for the six month period of 2007 primarily relates to stock based compensation expense of \$9.3 million, of which \$7.9 million was reversed in the third quarter of 2007 as a result of the termination of a consulting agreement. Under SFAS 123R, when a stock based compensation award is forfeited prior to vesting, all compensation expense recorded in previous periods is reversed in the period of forfeiture.

*Write-off of Acquired In-Process Research and Development.* On May 6, 2008, we acquired Vidus 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. On March 27, 2007, we acquired Acuity 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 \$243.8 million. We did not have any such activity during the 2008 period.

*Other operating expenses.* Other operating expenses primarily include amortization of our intangible assets acquired from OTI on November 28, 2007. We did not record any amortization expense during the first six months of 2007.

*Other Income and Expenses.* Other expense was \$0.5 million, net of \$0.2 million of interest income for the first six months of 2008 compared to \$0.2 million of interest expense for the 2007 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.

*Income taxes.* The income tax benefit for the first six months of 2008 reflects our estimated 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. We acquired OTI on November 28, 2007 and as a result, did not have similar refundable credits during the first six months of 2007.

## **LIQUIDITY AND CAPITAL RESOURCES**

At June 30, 2008, we had cash and cash equivalents of approximately \$5.5 million as compared to \$23.4 million at December 31, 2007. We used approximately \$15.5 million of cash in operations during the six months ended June 30, 2008. Cash was primarily used in our on-going Phase III clinical trial for bevasiranib and personnel costs supporting that trial and selling, general and administrative activities. Since our inception, we have not generated positive cash flow from operations and our primary source of cash has been from the private placement of stock and through credit facilities available to us.

On January 11, 2008, we repaid in full all outstanding amounts and terminated all of our commitments under the term loan with Horizon Financial Funding Company, LLC, or Horizon. The loan had an interest rate of 12.23%, and the

principal was payable in 12 equal monthly installments which commenced August 2007. The total amount repaid in satisfaction of our obligations under the term loan was \$2.4 million.

We currently have a fully utilized \$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. Phillip 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 10% annual rate, which is due July 11, 2009. The line of credit is collateralized by all of our personal property except our intellectual property.

On August 8, 2008, in exchange for a \$15 million cash investment in the Company, we agreed to issue 13,513,514 shares of our common stock, par value \$.01, to a group of investors which included members of The Frost Group. The shares will be issued at a price of \$1.11 per share, representing an approximately 40% discount to the average trading price of our stock on the American Stock Exchange. The shares issued in the private placement will be restricted securities, subject to a two year lockup, and no registration rights have been granted. Refer to Note 10.

We have not generated positive cash flow from operations, and 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 do not have the cash and cash equivalents on hand at June 30, 2008 sufficient to meet our anticipated cash requirements for operations and debt service for the next 12 months and we will require additional funding during the first half of 2009. If we accelerate our product development programs or initiate additional clinical trials, we will need additional funds earlier. Our future cash requirements will depend on a number of factors, including 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, and take other actions designed to reduce our cost of operations, all of which may not significantly extend the period of time that we will be able to continue operations without raising additional funding.

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, the issuance of debt or equity securities, debt financing and revenues from future product sales, if any. To the extent we raise additional capital by issuing equity securities or obtaining borrowings convertible into equity, ownership dilution to existing stockholders will result and future investors may be granted rights superior to those of existing stockholders. Other than as described in this section, we do not currently have any commitments for future external funding and there can be no assurance 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.

*Stock-Based Compensation.* As of June 23, 2006 (the date of inception), we adopted Statement of Financial Accounting Standards, or SFAS No. 123(R). Share-Based Payments SFAS No. 123(R) replaces SFAS No. 123, Accounting for Stock-Based Compensation, and supersedes APB No. 25. SFAS No. 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 No. 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 (SFAS No. 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 and OTI 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 No. 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, 2008 and December 31, 2007 was \$0.5 million and \$0.5 million, respectively.

*Recent accounting pronouncements:* 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 on an instrument-by-instrument basis.

In June 2007, the Emerging Issues Task Force (Task Force) of the FASB reached a consensus on Issue No. 07-3 ("EITF 07-3"), Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities. Under EITF 07-3, nonrefundable advance payments for goods or services that will be used or rendered for research and development activities should be deferred and capitalized. Such payments should be recognized as an expense as the goods are delivered or the related services are performed, not when the advance payment is made. If a company does not expect the goods to be delivered or services to be rendered, the capitalized advance payment should be charged to expense. EITF 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Earlier application is not permitted. We have adopted EITF 07-3 as of January 1, 2008. The adoption of EITF 07-3 did not have a material effect on our consolidated results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations. SFAS 141R will require, among other things, the expensing of direct transaction costs, including deal costs and restructuring costs as incurred, acquired in-process research and development assets to be capitalized, certain contingent assets and liabilities to be recognized at fair value and earn-out arrangements, including contingent consideration, may be required to be measured at fair

value until settled, with changes in fair value 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. SFAS No. 141R 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” (“SFAS No. 160”). SFAS No. 160 requires minority interests to be recharacterized as noncontrolling interests and reported as a component of equity. In addition, SFAS No. 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 No. 160 is effective for fiscal years beginning on or after December 15, 2008, with early adoption prohibited. We do not expect 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. 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, 2008, we had cash and cash equivalents of \$5.5 million. The weighted average interest rate related to our cash and cash equivalents for the year ended June 30, 2008 was 3.4%. As of June 30, 2008, the principal outstanding on our credit line was \$12.0 million, which bears a weighted average interest rate of 10.0%.

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, 2008. 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 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.

Beginning in the fourth quarter of 2007 and continuing through the first six months of 2008, we have implemented standards and procedures at OTI, upgrading and establishing controls over accounting systems, and adding employees who are trained and experienced in the preparation of financial statements in accordance with U.S. GAAP to ensure that we have in place appropriate internal control over financial reporting at OTI. Other than as set forth above with respect to OTI, there have been no changes to the Company’s internal control over financial reporting that occurred during the Company’s second quarter of 2008 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. The complaint sought damages for breach of fiduciary duty, intentional interference with contract and intentional interference with prospective economic advantage. On August 31, 2007, OIS filed a First Amended Complaint, re-alleging its claims and seeking damages in excess of \$7,000,000 from Mr. Verdooner. The Company agreed to indemnify Mr. Verdooner in connection with this action as a former officer. His employment with the Company was terminated on January 11, 2008.

On April 14, 2008, OIS was granted leave to file a Second Amended Complaint to add claims for tortious interference with contractual relations and prospective business advantage and aiding and abetting against the Company and The Frost Group, LLC. The Frost Group members include a trust controlled by Dr. Phillip Frost, the Company's Chief Executive Officer and Chairman, 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, the Chief Financial Officer of the Company. OIS filed the Second Amended Complaint on April 23, 2008, claiming in excess of \$7,000,000 in damages against the Company and the Frost Group for intentional interference, conspiracy and aiding and abetting, along with enhanced damages, injunctive relief and costs and attorneys' fees. The Company believes this action is without merit and is vigorously defending itself against the claims. Discovery is ongoing in this matter

#### **Item 1A. Risk Factors**

In addition to the other information set forth in this report, you should carefully consider the factors described in the "Risk Factors" section in our Annual Report on Form 10-K for the year ended December 31, 2007, which could materially affect our business, results of operations, financial condition or liquidity. The risks described in our Annual Report are not the only risk facing us. Additional risks and uncertainties not currently known to us or that we currently believe are immaterial also may materially adversely affect our business, results of operations, financial condition or liquidity. Other than as set forth below, there have been no material changes to the risks described in our Annual Report.

We do not have the cash and cash equivalents on hand at June 30, 2008 sufficient to meet our anticipated cash requirements for operations and debt service for the next 12 months, and we will require additional funding during the first half of 2009. We have based this estimate on assumptions that may prove to be wrong or subject to change, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on a number of factors, including 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.

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

On May 6, 2008, the Company completed the acquisition of all of the stock of Vidus Ocular, Inc. ("Vidus"), a privately-held company (the "Vidus Shares"). Pursuant to a Securities Purchase Agreement with Vidus, each of its stockholders, and the holders of convertible promissory notes issued by Vidus, the Company 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"); and (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"). Neither the Closing Shares or the Milestone Shares were registered under the Securities Act of 1933, as amended, and were offered in exchange for the Vidus Shares in reliance upon the exemption provided in Section 4(2) of the Securities Act for nonpublic offerings

#### **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 11, 2008.

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A. The election to the Board of Directors of the following nominees:

Name of Nominee	Number of Votes Cast For	Number of Votes Withheld
Phillip Frost, M.D.	141,067,653	125,844
Jane H. Hsiao, Ph.D.	140,825,239	368,258
Steven D. Rubin	141,067,996	125,501
Robert A. Baron	141,074,546	118,951
Thomas E. Beier	141,074,796	118,701
Pascal J. Goldschmidt, M.D.	141,062,808	130,689
Richard A. Lerner, M.D.	141,069,908	123,589
John A. Paganelli	141,065,396	128,101
Richard C. Pfenniger, Jr.	140,916,694	276,803
Michael Reich	140,882,899	310,598

### **Item 5. Other Information**

On August 5, 2008, the Audit Committee of the Board of Directors of the Company approved forms of indemnification agreements to be entered into with the directors and board-elected officers of the Company (the “Indemnification Agreements”). Pursuant to the Indemnification Agreements, the Company will indemnify the directors and board-elected officers from liability under specified circumstances, including without limitation, as a result of any claim asserted against such indemnitee, or as a resulting of any proceeding to which the indemnitee is named as a party, subject or witness, by reason of his or her serving on behalf of the Company.

The above summary of the Indemnification Agreements is qualified in its entirety by reference to the Indemnification Agreement forms attached to this Quarterly Report on Form 10-Q as Exhibits 10.1 and 10.2.

Pursuant to a Stock Purchase Agreement, dated as of August 8, 2008, a group of investors, which included members of The Frost Group, LLC, a private investment group controlled by Dr. Phillip Frost, M.D., Chairman and CEO of the Company, have agreed to make a \$15 million investment in the Company. Under the terms of the investment, the Company will issue to investors 13,513,514 shares of the Company’s common stock, par value \$.01 (the “Shares”), at \$1.11 per share, representing an approximately 40% discount to the five-day average closing price of the common stock on the American Stock Exchange (the “Investment”).

The Investment was approved by the Company’s Board of Directors and Audit Committee, and by stockholders holding a majority of the voting power of the outstanding capital stock of the Company. Stockholder approval was sought in order to comply with applicable rules of the American Stock Exchange. 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. The Company intends to file with the Securities and Exchange Commission and mail to stockholders an Information Statement informing our stockholders of the Investment and the approval of the issuance of the Shares. The Closing of the Investment and the issuance and delivery of the Shares is expected to occur approximately twenty (20) days after the mailing of the Information Statement to stockholders, which we currently anticipate will be on or around September 10, 2008.

The Shares issued in the Investment will be restricted securities, subject to a two year lockup, and no registration rights have been granted. The issuance of the Shares will be exempt from the registration requirements under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof, because the transaction does not involve a public offering.

In addition to Frost Gamma Investments Trust, of which Phillip Frost, M.D., is the sole trustee, The Frost Group also includes Dr. Jane Hsiao, Vice Chairman and Chief Technical Officer of OPKO, Dr. Rao Uppaluri, the Company's Chief Financial Officer, and Mr. Steven D. Rubin, the Company's Executive Vice President-Administration and a director.

**Item 6. Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
2.1 <sup>+</sup>	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.
3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation.
3.2 <sup>(2)</sup>	Amended and Restated By-Laws.
10.1	Form of Indemnification Agreement for Directors
10.2	Form of Indemnification Agreement for Officers
31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Exchange Act Rules 13a-14 and 15d-14.
31.2	Certification by Rao Uppaluri, Chief Financial Officer, pursuant to Exchange Act Rules 13a-14 and 15d-14.
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.
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.
<sup>(1)</sup>	Filed with the Company's Registration Statement on Form 8-A filed with the Securities and Exchange Commission on June 11, 2007, and incorporated herein by reference.
<sup>(2)</sup>	Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008 for the Company's fiscal year ended December 31, 2007, and incorporated herein by reference.
<sup>+</sup>	Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.

**SIGNATURES**

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

Date: August 8, 2008

**OPKO Health, Inc.**

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

EXHIBIT INDEX

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