Opko Health, Inc.
Form 10-Q
November 12, 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 September 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	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)

(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 x NO o

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

Large accelerated filer o	Accelerated filer 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 o NO x

As of November 4, 2008, the registrant had 198,730,753 shares of common stock, par value $0.01, outstanding.

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 and re-inspection of the OTI manufacturing facility in Toronto 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.

We may be unable to successfully defend litigation proceedings brought against us, and our financial condition could be adversely affected.

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 subsidiarie

Item 1. Financial Statements:

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

	September 30, 2008	December 31, 2007
ASSETS		
Current assets		
Cash and cash equivalents	$ 14,601	$ 23,373
Accounts receivable, net	2,079	1,689
Inventory	2,231	2,214
Prepaid expenses and other current assets	2,076	1,936
Total current assets	20,987	29,212
Property and equipment, net	616	410
Intangible assets, net	8,039	9,931
Other assets	166	15
Total assets	$ 29,808	$ 39,568
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 2,836	$ 3,319
Accrued expenses	6,015	3,858
Capital lease obligations and current portion of note payable	143	2,546
Total current liabilities	8,994	9,723
Long-term line of credit with related party, net of unamortized discount of $163 and $311, respectively	11,837	11,689
Long-term liabilities and capital lease obligations	3	1,372
Total liabilities	20,834	22,784
Commitments and contingencies		
Shareholders equity		
Series A Preferred stock $0.01 par value, 4,000,000 shares authorized; 867,051 and 954,799 shares issued and outstanding (liquidation value of $2,330 and $2,387) at September 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; 198,433,770 and 178,344,608 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	1,984	1,783
Additional paid-in-capital	306,512	284,273
Accumulated deficit	(299,531)	(269,282)

Total shareholders equity	8,974	16,784
Total liabilities and shareholders equity	$ 29,808	$ 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 and per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2008	2007	2008	2007
Revenue	$ 4,050	$	$ 7,753	$
Cost of goods sold	2,969		7,324	
Gross margin	1,081		429	
Operating expenses (reversal):				
Selling, general and administrative	3,722	2,722	12,284	8,151
Research and development	4,913	(4,496)	14,748	7,010
Write-off of acquired in-process research and development			1,398	243,761
Other operating expenses, principally amortization of intangible assets	427		1,281	
Total operating expenses (reversal)	9,062	(1,774)	29,711	258,922
Operating (loss) income	(7,981)	1,774	(29,282)	(258,922)
Other expense, net	(350)	(202)	(868)	(379)
(Loss) income before income taxes and loss from OTI	(8,331)	1,572	(30,150)	(259,301)
Income tax benefit	4		64	
Net (loss) income before loss from OTI	(8,327)	1,572	(30,086)	(259,301)
Loss from OTI		(91)		(126)
Net (loss) income	(8,327)	1,481	(30,086)	(259,427)
Preferred stock dividend	(53)	(41)	(163)	(164)
Net (loss) income attributable to common shareholders	$ (8,380)	$ 1,440	$ (30,249)	$ (259,591)
(Loss) income per share, basic	$ (0.04)	$ 0.01	$ (0.16)	$ (2.24)
(Loss) income per share, diluted	$ (0.04)	$ 0.01	$ (0.16)	$ (2.24)
Weighted average number of shares outstanding basic	187,625,641	162,793,526	184,361,260	116,034,500
Weighted average number of shares outstanding diluted	187,625,641	205,149,747	184,361,260	116,034,500

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

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

	For the nine months ended September 30,	
	2008	2007
Cash flows from operating activities		
Net loss	$ (30,086)	$ (259,427)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,366	17
Write-off of acquired in-process research and development	1,398	243,761
Provision for bad debts	70	
Inventory writedown	130	
Accretion of debt discount related to notes payable	156	154
Loss from investment in OTI		126
Share based compensation employees and non-employees	5,770	5,684
Changes in:		
Accounts receivable, net	(460)	
Inventory	(147)	
Prepaid expenses and other current assets	(142)	(431)
Other assets	(152)	(22)
Accounts payable	(611)	(720)
Accrued expenses and long-term liabilities	1,260	(236)
Net cash used in operating activities	(21,448)	(11,094)
Cash flows from investing activities		
Acquisition of OTI		(5,000)
Acquisition of businesses, net of cash	48	1,135
Capital expenditures	(284)	(208)
Net cash used in investing activities	(236)	(4,073)
Cash flows from financing activities:		
Issuance of common stock to related party	15,000	16,284
Borrowings under line of credit with related party		4,000
Insurance financing	327	
Proceeds from the exercise of stock options and warrants	351	72
Repayments of notes payable and capital lease obligations	(2,766)	(635)
Net cash provided by financing activities	12,912	19,721
Net (decrease) increase in cash and cash equivalents	(8,772)	4,554
Cash and cash equivalents at beginning of period	23,373	116
Cash and cash equivalents at end of period	$ 14,601	$ 4,670

SUPPLEMENTAL INFORMATION

Interest paid	$ 100	$ 245
NON-CASH INVESTING AND FINANCING ACTIVITES		
Issuance of common 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 nine month periods ended September 30, 2007 includes our minority interest results for Ophthalmic Technologies, Inc. (OTI), which we acquired on April 13, 2007. We acquired all 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 cash and cash equivalents on hand at September 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, 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.

As of September 30, 2008, we have a fully utilized $12.0 million line of credit with The Frost Group, LLC, or the Frost Group, a related party. 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. Effective November 6, 2008, the maturity date on the line of credit was extended for a period of eighteen months from July 11, 2009 until January 11, 2011, and the annual interest rate was increased to 11% from the amendment date forward.

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. Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control. The current disruptions in the U.S. and global financial markets may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Current economic conditions have been, and continue to be volatile and, in recent months, the volatility has reached unprecedented levels. Continued instability in these market conditions may limit our ability to

replace, in a timely manner, maturing liabilities and access the capital necessary to fund and grow our business. There can be no assurance that additional capital will be available to us on acceptable terms, or at all, which could adversely impact our business, results of operations, liquidity, capital resources and financial condition.

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 nine months ended September 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:

We adopted the provisions of SFAS 157, *Fair Value Measurements,* or SFAS 157, and SFAS 159, *The Fair Value Option for Financial Assets and Liabilities Including an Amendment of the FASB Statement No. 115,* or SFAS 159, 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 will defer the adoption of SFAS 157 for our nonfinancial assets and nonfinancial liabilities, except those items recognized or disclosed at fair value on an annual or more recurring basis, until January 1, 2009. The partial adoption of SFAS 157 did not have a material impact on our fair value measurements. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. We did not elect to adopt the fair value option for eligible financial instruments under SFAS 159.

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 September 30, 2008, 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. 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 September 30, 2008
	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	$ 14,315	$	$	$ 14,315
Total	$ 14,315	$	$	$ 14,315

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.

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 our 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 accounted for this acquisition as an asset acquisition. We valued the 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 unaudited pro forma results for the three month period ended September 30, 2007 and the nine month periods ended September 30, 2008 and September 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 September 30, 2007
Revenue	$
Net (loss) income attributable to common shareholders	$ 1,225
Basic (loss) income per share	$ 0.01
Diluted (loss) income per share	$ 0.01

(in thousands, except per share amounts)	For the nine months ended September 30, 2008	For the nine months ended September 30, 2007
Revenue	$ 7,753	$
Net loss attributable to common shareholders	$ (30,730)	$ (260,228)
Basic and diluted loss per share	$ (0.17)	$ (2.23)

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 20,139,831 common stock equivalents have been excluded from the calculation of net loss per share in the three months ended September 30, 2008, and a total of 24,617,550 and 29,105,008 common stock equivalents have been excluded from the calculation of net loss per share in the nine months ended September 30, 2008 and September 30, 2007, respectively, because their inclusion would be anti-dilutive.

NOTE 6 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(in thousands)	September 30, 2008	December 31, 2007
Accounts receivable, net:		
Accounts receivable	$ 2,364	$ 2,154
Less allowance for doubtful accounts	(285)	(465)
	$ 2,079	$ 1,689
Inventories, net		
Raw materials (components)	$ 1,458	$ 1,913
Work-in-process	350	
Finished products	553	301
Less inventory writedown	(130)	
	$ 2,231	$ 2,214
Intangible assets, net:		
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	(1,430)	(150)
Goodwill	1,120	1,732
	$ 8,039	$ 9,931

On November 28, 2007, we acquired 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. The plaintiff has also amended the 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 is vigorously defending itself against the claims. We are not able to determine 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. In September 2008, this employee notified us of his intent to exercise his put option. As a result, we have recorded the fair value of this option as an accrued expense in the amount of $58,000 at September 30, 2008. 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 September 30, 2008 based on the estimated fair value of this unexercised put option.

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 was not 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.

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. On September 18, 2008, we received a letter from the FDA stating that our responses to the warning letter indicated that we may have made adequate corrections to the deficiencies identified in the warning letter. A re-inspection by the FDA of the OTI facility in Toronto is necessary, however, before we can commence sales of the devices in the U.S. We currently anticipate the FDA s inspection during the fourth quarter of 2008.

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 and administrative services. The Lease is for a five-year term and currently requires annual rent of approximately $252,000, which amount increases by approximately 4.5% per year.

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, which required us to pay annual rent of $19,872 per year for the annex space, subject to annual increases. Effective October 1, 2008, we terminated this addendum and are no longer leasing this annex space.

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost in an amount equal to the cost of a first class airline ticket between the travel cities for each executive, including Dr. Frost, traveling on the airplane for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive; nor do we pay for any other fixed or variable operating costs of the airplane. During the three and nine months ended September 30, 2008, we reimbursed Dr. Frost approximately $5,000 and $91,000, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

During the three and nine months ended September 30, 2008, we reimbursed SafeStitch Medical, Inc. (SafeStitch) approximately $8,000 and $45,000, respectively, 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, 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. Effective November 6, 2008, the maturity date on the line of credit was extended for a period of eighteen months from July 11, 2009 until January 11, 2011, and the annual interest rate was increased to 11% from the amendment date forward. Refer to Note 12 of our Condensed Consolidated Financial Statements.

On September 10, 2008, we closed on a Stock Purchase Agreement with a group of investors including members of the Frost Group. Refer to Note 10.

On September 19, 2007, we entered into an exclusive technology license agreement with Winston Laboratories, Inc. (Winston). Under the terms of the license agreement, Winston granted us an exclusive license to the proprietary rights of certain products in exchange for the payment of an initial licensing fee, royalties, and payments on the occurrence of certain milestones. Subsequent to our entering into the license agreement with Winston, on November 13, 2007, Winston issued 5,815,851 shares of its Series A Preferred Stock and warrants to purchase 4,092,636 shares of its Series A Preferred Stock to a group of investors led by Dr. Frost, which also included Steven Rubin, our Executive Vice President-Administration, and Rao Uppaluri, the Company s Chief Financial Officer. In addition, effective the same day, Getting Ready Corporation, entered into a definitive Merger Agreement and Plan of Reorganization with Winston, now a wholly-owned subsidiary of Getting Ready Corporation. Getting Ready Corporation was a publicly held shell corporation of which approximately 42% was owned, prior to the merger with Winston, by Dr. Frost, Messrs. Rubin and Uppaluri and Jane Hsiao, our Vice Chairman and Chief Technical Officer (the Investors). Currently, the Investors beneficially own approximately 30% of Getting Ready, and Mr. Uppaluri has served as a member of Getting Ready s board of directors since September 2008.

NOTE 10 EQUITY OFFERING

Pursuant to a Stock Purchase Agreement, dated as of August 8, 2008, a group of investors, including members of the Frost Group, agreed to make a $15 million investment in the Company. Under the terms of the investment, the Company issued 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 occurred on September 10, 2008.

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

NOTE 11 MANUFACTURING FACILITY PURCHASE

On September 30, 2008, we entered into a purchase agreement to acquire a building in Hialeah, Florida to house manufacturing and service operations for our ophthalmic instrumentation business (the Facility). Since April 2008, we leased the Facility, which consists of approximately 20,000 square feet, pursuant to a lease agreement which provided us an option to purchase the Facility. According to the terms of the purchase agreement, we have agreed to pay approximately $1.6 million, net of certain credits for rent already paid in connection with our lease. The closing of the purchase is currently expected to occur on or before January 31, 2009.

NOTE 12 SUBSEQUENT EVENT

Effective as of November 6, 2008, we entered into an agreement with the Frost Group to extend the maturity date under our line of credit for an additional eighteen months from July 11, 2009 until January 11, 2011. In exchange for this extension, the Company agreed to increase the annual interest rate from 10% to 11% effective from the amendment date forward.

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 Cautionary Statement Regarding Forward-Looking Statements in Part I, Financial Information, and elsewhere in this Quarterly Report on Form 10-Q and 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 September 30, 2008, we had an accumulated deficit of $299.5 million. We do not currently generate revenue from any of our pharmaceutical product candidates and have only generated limited revenue from our instrumentation business. Our 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 SEPTEMBER 30, 2008 AND 2007

The three month period ended September 30, 2007 includes our minority interest results for Ophthalmic Technologies, Inc. (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 September 30, 2008 was $4.1 million. During the third quarter of 2008, we resumed shipping our ophthalmic instrumentation products to our international customers. We did not sell any products in the U.S. during the quarter ended September 30, 2008. Commencement of sales for our products in the U.S. will not occur until we have received clearance of the premarket notification 510(k) for our OCT/SLO device by the U.S. Food and Drug Administration (FDA) and the FDA has completed a satisfactory re-inspection of OTI s Toronto manufacturing facility. The increase in revenue during the three months ended September 30, 2008 from the first half of the year reflects international sales for our OCT/SLO and ultrasound products. We currently expect sales to continue to increase as we complete the transition of manufacturing our OCT/SLO product in-house and begin selling the OCT/SLO product in the U.S. Until the acquisition of OTI on November 28, 2007, we did not generate any revenue.

Gross margin. Gross margin for the three months ended September 30, 2008 was $1.1 million and was entirely related to our ophthalmic instrumentation product sales to our international customers. Gross margin benefited from lower cost of products sold as a result of changing a number of our suppliers for our OCT/SLO product as well as bringing more manufacturing processes in-house.

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Selling, general and administrative expense. Selling, general and administrative expense for the three months ended September 30, 2008 was $3.7 million compared to $2.7 million of expense for the comparable period of 2007. Selling, general and administrative expense for the three months ended September 30, 2008 primarily related to personnel costs, including stock-based compensation of $0.9 million and professional fees. The 2007 period primarily reflects personnel costs including approximately $0.8 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. following clearance of the pre-market notification 510(k) and re-inspection of OTI s Toronto facility by the FDA, we anticipate sales and marketing expenses will increase during the fourth quarter of 2008 and thereafter.

Research and development expense. Research and development expense during the three months ended September 30, 2008 was $4.9 million compared to a net reversal of expense of $4.5 million for the comparable period of 2007. The expense during the three months ended September 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 $0.7 million of stock-based compensation expense. The reversal of research and development expense for the 2007 three-month period relates to the reversal of stock based compensation expense of $8.1 million 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. Partially offsetting this reversal of stock based compensation expense are costs related to the initiation of our Phase III clinical trial, primarily personnel costs and start-up fees for our clinical sites.

Other operating expenses. Other operating expenses of $0.4 million for the three months ended September 30, 2008 reflects amortization of intangible assets acquired from OTI on November 28, 2007. We did not record any amortization expense during the quarter ended September 30, 2007.

Other income and expenses. Other expense was $0.4 million reflecting interest on our outstanding line of credit for the three months ended September 30, 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 borrowings.

Income taxes. The income tax benefit for the three months ended September 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 September 30, 2007.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2008 AND 2007

The nine month period ended September 30, 2008 includes our operations, as well as the operations of OTI, which we acquired on November 28, 2007. The nine months ended September 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 nine months ended September 30, 2008 was $7.8 million. All revenue was generated from sales of OTI s ophthalmic instrumentation products. We shipped a limited number of products to international markets during the second quarter of 2008, as we shut down production to correct issues cited by the FDA in its March 25, 2008 warning letter to OTI. We resumed production and shipments of our products to international customers during the third quarter of 2008. 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 nine 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 and the FDA has completed a satisfactory re-inspection of OTS s Toronto manufacturing facility We anticipate revenue will increase as we move production of components for the OCT/SLO in-house and begin selling the OCT/SLO product in the U.S..

Gross margin. Gross margin for the nine months ended September 30, 2008 was $0.4 million and was entirely related to our ophthalmic instrumentation product sales. The gross margin was negatively impacted by manufacturing costs associated with the introduction of our new OCT/SLO model internationally while we changed suppliers and moved production of our OCT/SLO in-house. During the nine month period ended September 30, 2008, 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 nine months ended September 30, 2008 was $12.3 million compared to $8.2 million of expense for the comparable period of 2007. Selling, general and administrative expense for the nine months ended September 30, 2008 primarily related to personnel costs, including stock-based compensation of $3.8 million and professional fees. In addition, as a result of our acquisition of OTI on November 28, 2007, our selling expenses reflect a full nine months of post acquisition activity for OTI. As we prepare to sell OTI s OCT/SLO product in the U.S. following clearance of the pre-market notification 510(k) and re-inspection of OTI s Toronto facility by the FDA, 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 $3.4 million of expense related to stock-based compensation and professional fees.

Research and development expense. Research and development expense during the nine months ended September 30, 2008 was $14.7 million compared to $7.0 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 nine month period of 2008 was $1.9 million in stock based compensation expense. Research and development expense for the nine month period of 2007 primarily relates to personnel costs, including stock based compensation expense of $2.3 million and costs related to the initiation of our Phase III clinical trial. The three months ended September 30, 2007 included a reversal of stock based compensation expense of $8.1 million as a result of the termination of a consulting agreement which had been expensed in prior quarters. 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.

Other operating expenses. Other operating expenses of $1.3 million reflect amortization of our intangible assets acquired from OTI on November 28, 2007. We did not record any amortization expense during the first nine months of 2007.

Other income and expenses. Other expense was $0.9 million, net of $0.3 million of interest income for the first nine months of 2008 compared to $0.4 million of interest expense, net of $0.2 million 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 borrowings.

Income taxes. The income tax benefit for the first nine 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 nine months of 2007.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2008, we had cash and cash equivalents of approximately $14.6 million as compared to $23.4 million at December 31, 2007. We used approximately $21.4 million of cash in operations during the nine months ended September 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. Effective November 6, 2008, the maturity date on the line of credit was extended for a period of eighteen months from July 11, 2009 until January 11, 2011, and the annual interest rate was increased to 11% from the amendment date forward. Refer to Note 12 of our Condensed Consolidated Financial Statements

On September 10, 2008, in exchange for a $15 million cash investment in the Company, we issued 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 were 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 are restricted securities, subject to a two year lockup, and no registration rights have been granted. Refer to Note 10 of our Condensed Consolidated Financial Statements.

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 September 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, 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. Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control. The current disruptions in the U.S. and global financial markets may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Current economic conditions have been, and continue to be volatile and, in recent months, the volatility has reached unprecedented levels. Continued instability in these market conditions may limit our ability to replace, in a timely manner, maturing liabilities and access the capital necessary to fund and grow our business. 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 September 30, 2008 and December 31, 2007 was $0.3 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-our 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 funds. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment. At September 30, 2008, we had cash and cash equivalents of $14.6 million. The weighted average interest rate related to our cash and cash equivalents for the year ended September 30, 2008 was 3.1%. As of September 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 September 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 nine 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 third 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 23, 2008, OIS filed 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. In September 2008, the court granted the demurrer requested by the Frost Group, and by the Company on certain counts, with leave to amend. Plaintiffs filed a Third Amended Complaint on or around October 10, 2008. OIS has claimed in excess of $7,000,000 in damages against the Company and the Frost Group for intentional interference and aiding and abetting, along with enhanced damages, injunctive relief and costs and attorneys fees. The Company 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 September 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, and our success in developing markets for our product candidates.

Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control. The current disruptions in the U.S. and global financial markets may adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Current economic conditions have been, and continue to be volatile and, in recent months, the volatility has reached unprecedented levels. Continued instability in these market conditions may limit our ability to replace, in a timely manner, maturing liabilities and access the capital necessary to fund and grow our business. There can be no assurance that additional capital will be available to us on acceptable terms, or at all, which could adversely impact our business, results of operations, liquidity, capital resources and financial condition.

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

On September 10, 2008, a group of investors including members of The Frost Group, LLC, a private investment group controlled by Phillip Frost, M.D., our Chairman and CEO, made a $15 million investment in the Company. Under the terms of the investment, we issued 13,513,514 shares of common stock, par value $.01, at $1.11 per share, representing an approximately 40% discount to the average trading price of the Company s stock on the American Stock Exchange for the five trading days immediately preceding the effective date of board and stockholder approval of the investment. The shares issued in the investment are restricted securities, subject to a two year lockup, and no registration rights were granted. The issuance of the shares was exempt from the registration requirements under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof, because the transaction did 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 3. Defaults Upon Senior Securities

None.

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

Effective as of August 7, 2008, stockholders holding a majority of the voting power of the Company s outstanding capital stock approved the issuance to a group of investors, including members of the Frost Group, a private investment group controlled by Phillip Frost, M.D., our Chairman and CEO, of an aggregate of 13,513,514 shares (the Shares) of the Company s common stock, par value $0.01 per share, in exchange for a $15 million investment in 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 American Stock Exchange, on which our common stock is listed.

Item 5. Other Information

On November 6, 2008, we entered into an amendment to our $12.0 million line of credit with the Frost Group, a related party. The amendment extends the maturity date on the line of credit for a period of eighteen months from July 11, 2009 until January 11, 2011, and increases the annual interest rate from 10% to 11% from the amendment date forward. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit, which as of September 30, 2008 is $12.0 million. The line of credit is collateralized by all of our personal property except our intellectual property. 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.

Item 6. Exhibits.

Exhibit Number	Description
2.1[(1)]+	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[(2)]	Amended and Restated Certificate of Incorporation
3.2 [(3)]	Amended and Restated By-Laws.
10.1	Stock Purchase Agreement, dated August 8, 2008 by and among the Company and the Investors named therein.
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.

(1) Filed with the Company s Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 5, 2008.

(2) 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.

(3) 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.

+ 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: November 10, 2008

OPKO Health, Inc.

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

EXHIBIT INDEX

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