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	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 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 o NO x

As of July 30, 2008, the registrant had 184,651,391 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 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.
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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
ASSETS		
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
LIABILITIES AND SHAREHOLDERS' EQUITY		
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