

**SECURITIES AND EXCHANGE COMMISSION**

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**PART I. FINANCIAL INFORMATION**

Item 1. Financial Statements:

[This section contains 20 horizontal lines for providing financial statements.]



**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 in “Item 1A-Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2007 and described from time to time in our reports filed with the Securities and Exchange Commission. We do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. ~~Reg LRA~~ <sup>LRA</sup> ~~Reg LRA~~ <sup>Read</sup>

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- 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 da



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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]





**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 business presently consists of the development of ophthalmic pharmaceuticals and the development, commercialization and sale of ophthalmic diagnostic and imaging systems and instrumentation products. Our objective is to establish industry-leading positions in large and rapidly growing segments of ophthalmology by leveraging our preclinical and development expertise and our novel and proprietary technologies. We actively explore opportunities to acquire complementary pharmaceuticals, compounds, and technologies, which could, individually or in the aggregate, materially increase the scale of our business. We also intend to explore strategic opportunities in the future.



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 a material 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,

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Upon the termination of an employee of OTI, we became obligated at the former employee's sole option to acquire up to 10% of the shares issued to the employee in connection with the acquisition of OTI at a price of \$3.55 per share. The total potential obligation for this former employee is approximately \$0.1 million. In addition, an existing employee of OTI has the same provision within his employment arrangement with a potential obligation of approximately \$0.3 million. We have recorded approximately \$0.2 million as of March 31, 2008 based on the estimated fair market value of these put options as an accrued expense.

On March 25, 2008, OTI received a warning letter in connection with a FDA inspection of OTI's Toronto facility in July and August of 2007. The warning letter cited several deficiencies in OTI's quality, record keeping, and reporting systems relating to certain of OTI's products, including the OTI Scan 1000, OTI Scan 2000, and OTI OCT/SLO combination imaging system. Based upon the observations noted in the warning letter, OTI is not currently in compliance with cGMP. The FDA indicated that it has issued an Import Alert and may refuse admission of the

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## **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 report and in our Annual Report on Form 10-K for the year ended December 31, 2007 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part II, 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 business presently consists of the development of ophthalmic pharmaceuticals and the development, commercialization and sale of ophthalmic diagnostic and imaging systems and instrumentation products. Our objective is to establish industry-leading positions in large and rapidly growing segments of ophthalmology by leveraging our preclinical and development expertise and our novel and proprietary technologies. We actively explore opportunities to acquire complementary pharmaceuticals, compounds, and technologies, which could, individually or in the aggregate, materially increase the scale of our business. We also intend to explore strategic opportunities in other medical markets that would allow us to benefit from our business and global distribution expertise, and which have operational characteristics that are similar to ophthalmology, such as dermatology.

We expect to incur substantial losses as we continue the development of our product candidates, 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 March 31, 2008, we had an accumulated deficit of \$280.2 million. Since we do not generate revenue from any of our pharmaceutical product candidates and have only generated limited revenue from our instrumentation business, we expect to continue to generate losses in connection with the continued clinical development of bevasiranib and the research and development activities relating to our technology and other product candidates. Such research and development activities are budgeted to expand over time and will require further resources if we are to be successful. As a result, we believe that our operating losses are likely to be substantial over the next several years. We will need to obtain additional funds to further develop our research and development programs, and there can be no assurance that additional capital will be available to us on acceptable terms, or at all.

### **RESULTS OF OPERATIONS**

#### **FOR THE THREE MONTHS ENDED MARCH 31, 2008 AND 2007**

The results for the period ended March 31, 2007 include Fropitix's results for the full period and the results of operations from Acuity Pharmaceuticals, Inc., or Acuity, subsequent to our acquisition on March 27, 2007. The three month period ended March 31, 2008 includes the operations of both Fropitix and Acuity as well as the operation of OTI, which we acquired in November 28, 2007.

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We do not believe the cash and cash equivalents on hand at March 31, 2008 will be 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 second half of the year. We based this estimate on assumptions that may prove to be wrong or subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we accelerate our product development programs or initiate additional clinical trials, we will need additional funds 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 approval, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the availability of financing, and our success in developing markets for our product candidates. To secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our research and development programs.

We intend to finance additional research and development projects, clinical trials and our future operations through a combination of private placements, payments from potential strategic research and development licensing and/or partnering arrangements, and revenues from future product sales, if any. We do not currently have any commitments for financing and there can be no assurance that additional capital will be available to us on acceptable terms.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

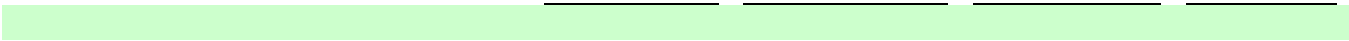
*Accounting Estimates.* The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and the reported amounts of sales and expenses. Results could differ from those estimates.

Statement of Financial Position

*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 internatio

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**Item 6. Exhibits.**

**Exhibit  
Number**

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## EXHIBIT INDEX

- 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.

**CERTIFICATIONS**

I, Phillip Frost, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2008

/s/ Phillip Frost  
Phillip Frost, M.D.  
Chief Executive Officer

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**CERTIFICATIONS**

I, Rao Uppaluri, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health, Inc.;
  - (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  - (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  - (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter) or if " " " " " "
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**Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002  
(Subsections (a) and (b) of Section 1350, Chapter 73 of Title 18, United**

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