

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

**FORM 10-Q**

(Mark One)

- QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2007.

**OR**

- TRANSITION REPORT UNDER 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.**

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**PART I. FINANCIAL INFORMATION**

Item 1. e

[Redacted content]

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## **PART I. FINANCIAL INFORMATION**

### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This report contains “forward-looking statements,” as that term is defined under Private Securities Litigation Reform Act of 1995, or PSLRA. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business

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OPKO Health, Inc.  
CONDENSED CONSOLIDATED STATEMENTS SHAREHOLDERS' (DEFICIT) EQUITY  
(A Development Stage Company)  
(in thousands except share data)  
For the cumulative period from inception (June 23, 2006) to September 30, 2007  
(unaudited)

<u>Series A</u> <u>Preferred Stock</u>	<u>Series C</u> <u>Preferred Stock</u>	<u>Common Stock</u>	<u>Additional</u> <u>Paid-In</u>	<u>Accumulated</u>
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. On March 27, 2007, the Company purchased Acuity's assets in a stock for stock transaction. We valued our common stock issued to Acuity shareholders at the average closing price of the common stock on the date of acquisition and the twahas

[Redacted]

[Redacted]

[Redacted]



### Note 3 Summary of Significant Accounting Policies

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. However, 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 for the three and nine months ended September 30, 2007 and cash flows for the nine months ended September 30, 2007, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2007 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 Current Report on Form 8-K filed as a result of the Merger on March 27, 2007. Refer to Note 1.

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.

We consider all non-restrictive, highly liquid short-term investments purchased with a maturity of three months or less on the date of purchase to be cash equivalents.

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, generally five to ten years. Expenditures for repairs and maintenance are charged to expense as incurred, while betterments are capitalized.

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. As of September 30, 2007, we believe that no impairment charge on long-lived assets is required.

Research and product development costs are charged to expense as incurred. We record expenses for research and development as those that had not reached technological feasibility and which had no alternative use.

Income taxes are accounted for undtsi a



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#### Note 4 Debt

On January 11, 2007, Acuity entered into an agreement with the Frost Group whereby the Frost Group provided a subordinated secured line of credit of up to \$7.0 million to Acuity. 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. In exchange for entering into this agreement, Acuity agreed to grant to the Frost Group a warrant to purchase up to 125,000 shares of Acuity Series B Preferred Stock, par value \$0.01 per share, for an exercise price of \$2.00 per share, which upon consummation of the Merger converted into 6,478 shares of our Series C Preferred stock and a warrant to purchase up to 15,625 shares of Acuity Common Stock, for an exercise price of \$0.01 per share, which converted upon the Merger to 81,085 warrants to purchase shares of our Common Stock. On June 22, 2007, the Series C preferred stock automatically converted to 647,800 shares of our common stock.

In connection with the consummation of the Mergers, we assumed the rights and obligations of Acuity under this line of credit. We also amended and restated this line of credit to provide additional available borrowing capacity. Under this amended and restated line of credit, the line of credit was increased to \$12.0 million and we assumed Acuity's existing obligation to repay \$4.0 million outstanding under the prior line of credit. In September 2007, we drew down an additional \$4.0 million for a total of \$8.0 million borrowed and \$4.0 million available to be borrowed. We are obligated to pay interest upon maturity, compounded quarterly on borrowings under the line of credit at a 10% annual rate, which is due on July 11, 2009. The line of credit is collateralized by all of our personal property, except intellectual property. In connection with the assumption and amendment of the line of credit, we granted warrants to purchase 4,000,000 shares of our common stock to the Frost Group. The fair value of the warrants was determined to be \$12.4 million using the Black-Scholes option valuation model. Because the issuance of the warrants and the increase in the line of credit were conditioned upon the completion of the Mergers, the value of the warrants has been allocated on a relative fair value basis to the cost of the Acuity acquisition (\$1.3 million), the cost of the reverse merger between Froptix and (Froptix) (\$11.0 million) and debt commitment fee (\$0.1 million).

We assumed the rights and obligations of Acuity's \$4.0 million term loan with Horizon Financial, Inc., in connection with the Mergers. The term loan bears interest at 12.23%, which is payable monthly commencing September 15, 2005. The principal is payable in 12 equal monthly installments commencing August 15, 2005. The term loan is secured by the assets of Acuity and the Mergers.













We may redeem the outstanding shares of Series A preferred stock for \$2.50 per share (plus accrued and unpaid dividends), at any time.

### **Series C Preferred Stock**

Of the authorized preferred stock, 500,000 shares were designated Series C preferred stock. On June 22, 2007, 457,584 Series C preferred stock were issued and outstanding and held by 30 stockholders. Cumulative dividends were payable on the Series C preferred stock in the amount of \$1.54 per share when declared by the board of directors. On June 22, 2007, all of the shares of Series C preferred stock automatically converted into shares of common stock, on a one-hundred-for-one basis (subject to adjustment as noted above), as our common stock traded above the \$3.83 conversion per share price on the American Stock Exchange for ten consecutive days.

### **Anti-Takeover Effects of Certain Provisions of our Certificate of Incorporation, our By-Laws and Delaware Law**

#### **Delaware Statute.**

We are subject to Section 203 of the Delaware General Corporation law, which prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to such date, our board of directors approves either the business combination or the transaction that resulted in the stockholder’s becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owns at least 85% of our outstanding voting stock, excluding shares held by directors, officers and certain employee stock plans; or
- on or after the consummation date, the business combination is approved by our board of directors and by the affirmative vote at an annual or special meeting of stockholders holding of at least two-thirds of our outstanding voting stock that is not owned by the interested stockholder.

For purposes of Section 203, a “business combination” includes, among other things, a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an “interested stockholder” is generally a person who, together with affiliates and associates of such person:

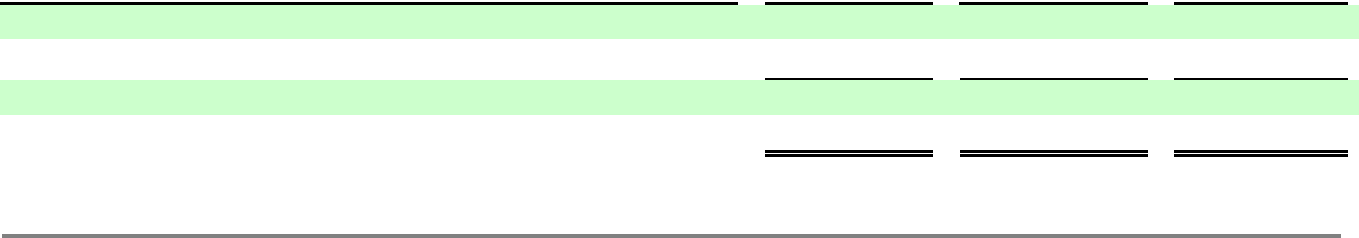
- owns 15% or more of outstanding voting stock; or
- is an affiliate or associate of ours and was the owner of 15% or more of our outstanding voting stock at any time within the prior three years.

#### **Certificate of Incorporation and Bylaw Provisions.**

Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that, among others, could have the effect of delaying, deferring, or discouraging potential acquisition proposals and could delay or prevent a change of control of us. The provisions in our certificate of incorporation and bylaws that may have such effect include:

- As noted above, our board of directors, without stockholder approval, has the authority under our certificate of incorporation to issue preferred stock with rights superior to the rights of the holders of common stock. As a result, we could issue preferred stock quickly and easily, which could adversely affect the rights of holders of our common stock and could be issued with terms calculated to delay or prevent a change of control or make removal of management more difficult.
- Directors may be removed by the affirmative vote of the holders of at least a majority of the voting power of all of the outstanding shares of capital stock of the corporation entitled to vote thereon, voting together as a single class.

. Under our certificate of incorporation and bylaws, special meetings of our stockholders may be called only by the vote of a majority of the entire board. Our stockholders may not call a special meeting of the stockholders.



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

### **OVERVIEW**

We are a specialty healthcare company focused on the discovery, development, and commercialization of proprietary pharmaceuticals, drug delivery technologies, diagnostic systems and instruments for the treatment, diagnosis and prevention of ophthalmic diseases. We are still a development stage company and have generated significant losses since our inception in June 2006. Our lead pharmaceutical product candidate in clinical development is bevasiranib for the treatment of wet age-related macular degeneration ("Wet AMD"). We intend to expand our current operations by acquiring additional ophthalmic businesses and therapeutic and diagnostic technologies, as well as exploring opportunities in other medical markets that have operational characteristics 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 substantially all of our efforts towards research and development. As of September 30, 2007, we had an accumulated deficit of \$260.5 million. Since we do not generate revenue from any of our pharmaceutical product candidates, 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.

On June 8, 2007, we changed our name to OPKO Health, Inc., or OPKO, from \_\_\_\_\_, Inc., or \_\_\_\_\_. On March 27, 2007, we were part of a three-way merger between Fropix Corporation, or Fropix, a research and development company, \_\_\_\_\_, a shell public company, and Acuity Pharmaceuticals, Inc., or Acuity, a research and development company. This transaction was accounted for as a reverse merger between Fropix and \_\_\_\_\_, with the combined company then acquiring Acuity. \_\_\_\_\_, Inc., formerly known as Cytoclonal Pharmaceuticals Inc., was previously involved in the research, creation, and development of drugs for the treatment and/or prevention of cancer and infectious diseases, however, \_\_\_\_\_ had been a public shell company without any operations since 2003.

On April 13, 2007, we invested \$5.0 million in Ophthalmic Technologies, Inc., or OTI, an Ontario corporation pursuant to a definitive Share Purchase Agreement (the "Purchase Agreement") with OTI and its shareholders. In exchange for the \$5.0 million investment, OTI issued common shares of OTI to us to cause us to hold one-third OTI's share capital on a fully diluted basis and we received an exclusive option to purchase the remaining shares of OTI in exchange for the issuance of between 3.13 million and 2.82 million shares of our common stock, depending upon the average per share closing price of our common stock for the ten (10) trading dates ended on the second business day prior to the exercise of the option. The \$5.0 million is being used by OTI for working capital. We have elected to exercise the option to acquire the remaining shares of OTI and are negotiating definitive transaction documents relating to the acquisition.



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In September 2006, the FASB issued SFAS



No significant changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934) occurred during the quarter ended September 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. Risk Factors

The occurrence of any of the events discussed below could significantly and adversely affect our business, prospects, results of operations, financial condition and cash flows:

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

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In addition, the results of our clinical trials may show that our product candidates may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities.

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment ave rehug prodaut ugróřsæ



We believe that our ability to successfully compete will depend on, among other things:

- the results of our clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety and reliability of our product candidates;
- the speed at which we develop our product candidates;
- our ability to commercialize and market any of our product candidates that may receive regulatory approval or clearance;
- our ability to design and successfully execute appropriate clinical trials;
- the timing and scope of regulatory approvals or clearances;
- appropriate coverage and adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our products;
- our ability to have our partners manufacture and sell commercial quantities of any approved products to the market; and
- acceptance of future product candidates by physicians and other health care providers.

If our competitors market products that are more effective, safer, easier to use or less expensive than our future product candidates, if any, or that reach the market sooner than our future product candidates, if any, we may not achieve commercial success. In addition, both the biopharmaceutical and medical device industries are characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technology obsolete.

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Regulatory approval of an NDA or NDA supplement, PMA, PMA supplement or clearance pursuant to a pre-market notification is not guaranteed, and the approval or clearance process, as the case may be, is expensive and may, especially in the case of an NDA or PMA application, take several years. The FDA also has substantial discretion in the drug and medical device approval and clearance process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA approval or clearance varies depending on the drug or medical device candidate, the disease or condition that the drug or medical device candidate is designed to address, and the regulations applicable to any particular drug or medical device candidate. The FDA can delay, limit or deny approval or clearance of a drug or medical device candidate for many reasons, including:

~~Minimal NDA candidate may not be deemed safe or effective.~~

- a medical device candidate may not be deemed to be substantially equivalent to a lawfully marketed non-PMA device, in the case of a premarket notification.
- FDA officials may not find the data from pre-clinical studies and clinical trials sufficient;
- the FDA might not approve our third-party manufacturer's processes or facilities; or
- the FDA may change its approval or clearance policies or adopt new regulations.

The Company may, at some future date, seek approval of one or more drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, § 505(b)(2) which permits a manufacturer to submit an NDA for an existing drug compound for intended uses that have already been approved by the FDA, but with certain different characteristics, such as a different route of administration. Section 505(b)(2) allows a company to reference the clinical data already collected by the NDA <sup>applicant</sup> ~~structure~~ s

- regulatory authorities may withdraw their approval of the product and require us to take our approved drug off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may have limitations on how we promote our drugs;
- sales of products may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

**Even if we obtain regulatory approvals or clearances 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.**

Once regulatory approval has been granted, the approved or cleared product and its manufacturer are subject to continual review. Any approved or cleared product may only be promoted for its indicated uses. In addition, if the FDA or other non-United States regulatory authorities approve any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive regulatory requirements. We and the manufacturers of our products are also required to comply with current Good Manufacturing Practicing, or cGMP regulations, or the FDA's Quality System Regulation, or QSR regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Moreover, device manufacturers are required to report adverse events by filing Medical Device Reports with the FDA, which reports are publicly available. Further, regulatory agencies must approve manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and other non-United States regulatory authorities, or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions.

In addition, the FDA and other non-United States regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay regulatory approval or clearance of the product.





- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of our future product candidates, both in absolute terms and relative to alternative treatments;
- availability of coverage and reimbursement from government and other third-party payors;
- potential product liability claims;
- limitations or warnings contained in a product's FDA-approved labeling; and
- changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval.

In addition, our efforts to educate the medical community and health care payors on the benefits of our product candidates may require significant resources and may never be successful.

**If our future product candidates fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability.**

The coverage and reimbursement status of newly approved or cleared drugs or medical devices is uncertain, and failure of our pharmaceutical products and procedures using our medical devices to be adequately covered by insurance and eligible for adequate reimbursement could limit our ability to market any future product candidates we may develop and decrease our ability to generate revenue from any of our existing and future product candidates that may be approved or cleared.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved or cleared drugs or medical devices. Normally, surgical devices are not directly covered by insurance; instead, the procedure using the device is subject to a coverage determination by the insurer. The commercial success of our existing and future product candidates in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations, and other third-party payors. The government and other third-party payors are increasingly attempting to contain health care costs by limiting both insurance coverage and the level of reimbursement for new drugs or devices and, as a result, they may not cover or provide adequate payment for our existing and future product candidates. These payors may conclude that our future product candidates are less safe, less effective or less cost-effective than existing or later-introduced products. These payors may also conclude that the overall cost of the procedure using one of our devices exceeds the overall cost of the competing procedure using another type of device, and third-party payors may not approve our future product candidates for insurance coverage and adequate reimbursement. The failure to obtain coverage and adequate or any reimbursement for our existing and future product candidates, or health care cost containment initiatives that limit or restrict reimbursement for our existing and future product candidates, may reduce any future product revenue. Even though a drug (formally administered by a physician) may be approved by the FDA, this does not mean that a Prescription Drug Plan, or PDP, a private insurer operating under Medicare part D, will list that drug on its formulary or will set a reimbursement level. PDPs are not required to make every FDA-approved drug available on their formularies. If our drug products are not listed on sufficient number of PDP formularies or if the PDPs' levels of reimbursement are inadequate, the Company could be materially adversely affected.

**If we fail to attain 9MP**



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**We currently have limited marketing staff, no pharmaceutical sales or distribution capabilities and have only recently commenced developing medical device sales capabilities in the United States. If we are unable to develop our pharmaceutical sales and marketing and distribution capability and our medical device sales and marketing capabilities in the United States on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical product candidates or our medical device product candidates in the United States.**

We currently have no pharmaceutical marketing, sales or distribution capabilities. We have only recently commenced developing medical device sales capabilities in the United States. If our pharmaceutical product candidates are approved, we intend to establish our sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming. Any failure or delay in the development of any of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products. With respect to our existing and future pharmaceutical product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue is likely to be lower than if we directly marketed or sold our products. In addition, any revenue we receive will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our existing and future product candidates. If we are not successful in commercializing our existing and future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

**Independent clinical investigators SS M**

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**If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed.**

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our proposed products. Because certain United States patent applications are confidential until patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date for which nonpublication has been requested, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third-party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we may not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third-party patent or otherwise circumvent the third-party patent.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. In addition, we will rely on third-party collaborators to file patent applications relating to proprietary technology that we develop jointly during certain collaborations. The process of obtaining patent protection is expensive and time-consuming. If our present or future collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business will be adversely affected. Despite our efforts and the efforts of our collaborators to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The issuance of a patent does not guarantee that it is valid or enforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, unenforceable or circumvented. Moreover, the United States Patent and Trademark Office, or USPTO, may commence interference proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology, pharmaceutical and medical device companies.

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical, biotechnology and medical device companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical, biotechnology or medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our owned or licensed patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications, those we may file in the future, or those we may license from third parties, including the University of Pennsylvania, the University of Illinois, the University of Florida Research Foundation and our overseas

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While we believe that our patent rights are enforceable, we cannot assure you that any patents that have issued, that may issue or that may be licensed to us will be enforceable or valid or will not expire prior to the commercialization of our product candidates, thus allowing others to more effectively compete with us. Therefore, any patents that we own or license may not adequately protect our product candidates or our future products.

**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.**

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

**We will rely heavily on licenses from third parties.**

Many of the patents and patent applications in our patent portfolio are not owned by us, but are licensed from third parties. For example, we rely on technology licensed from the University of Pennsylvania, the University of Illinois, the University of Florida Research Foundation and Intradigm. Such license agreements give us rights for the commercial exploitation of the patents resulting from the respective patent applications, subject to certain provisions of the license agreements. Failure to comply with these provisions could result in the loss of our rights under these license agreements. Our inability to rely on these patents and patent applications which are the basis of our technology would have a material adverse effect on our business.

**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.**

We have obtained licenses from, among others, the University of Pennsylvania, the University of Illinois, the University of Florida Research Foundation and Intradigm that are necessary or useful for our business. In addition, we intend to enter into additional licenses of

Patent applications filed by



Some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended (c







- diversion of management's attention in connection with both negotiating the acquisitions and integrating the businesses;
- strain on managerial and operational resources as management tries to oversee larger operations;
- exposure to unforeseen liabilities of acquired companies;
- potential costly and time-consuming litigation, including stockholder lawsuits;
- potential issuance of securities to equity holders of the company being acquired with rights that are superior to the rights of holders of our common stock, or which may have a dilutive effect on our stockholders;
- the need to incur additional debt or use cash; and
- the requirement to record potentially significant additional future operating costs for the amortization of intangible assets.

As a result of these or other problems and risks, businesses we acquire may not ~~produce~~ the re' ese or othe er

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

As of November 9, 2007, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, owned more than 50% of our outstanding voting securities. As a result, if some or all of them acted together, they would have the ability to control the election of our Board of Directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices.

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

There have been changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new regulations promulgated by the Securities and Exchange Commission and rules promulgated by the American Stock Exchange, the other national securities exchanges and the NASDAQ. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Our board members, Chief Executive Officer, Chief Financial Officer and Principal Accounting Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, we could be subject to liability under applicable laws or our reputation may be harmed.

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

None.

Item 3. Defaults Upon Senior Securities

None.

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

None.

Item 5. Other Information

None.

Item 6. Exhibits.

Exhibit 10.1 Office leased Dated November \_\_, 2007 by and between Frost Real Estate Holdings LLC, a Florida limited liability company and OPKO Health, Inc.

Exhibit 31.1 Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2007.

Exhibit 31.2 Certification by Rao Uppaluri, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2007.

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**OFFICE LEASE**

**1. Basic Lease Provisions.**

- 1.1. **Parties:** This Lease is made and entered into as of the 13<sup>th</sup> day of November 2007 (the "Effective Date") by and between FROST REAL ESTATE HOLDINGS, LLC, a Florida limited liability company ("Landlord"), and OPKO HEALTH, INC., a Delaware corporation ("Tenant").
- 1.2. **Premises:** Suite Numbers 1500 and 1180, as shown on Exhibit "A" attached hereto (the "Premises").
- 1.3. **Rentable Square Footage of the Premises:** 8,320 Square feet (3,245 SF on 15<sup>TH</sup> Floor-North + 5,075 on 11<sup>th</sup> Floor North). Landlord and Tenant stipulate and agree that the rentable square footage of the Premises is correct.
- 1.4. **Building Address:** 4400 Biscayne Boulevard, Miami, Florida 33137.
- 1.5. **Permitted Use:** General office use in the 15<sup>th</sup> and 11<sup>th</sup> floor office space, subject to the requirements and limitations contained in Section 6.
- 1.6. **Term:** Five (5) years.
- 1.7. **Commencement Date:** August 1, 2007.
- 1.8. **Rent:** Tenant shall make rent payments under this Lease on a "gross" basis (the "Rent"), plus applicable sales tax. The rent shall be increased annually by four and one half percent (4.5%) on each anniversary date as follows:

<b>Lease Period in Months</b>	<b><u>Annual Rent</u></b>
August 1, 2007- July 31, 2008	<b>\$211,280</b>
August 1, 2008- July 31, 2009	<b>\$252,138</b>
August 1, 2009- July 31, 2010	<b>\$263,484</b>
August 1, 2010- July 31, 2011	<b>\$275,341</b>
August 1, 2011- July 31, 2012	<b>\$287,731</b>

- 1.9. **Intentionally Omitted.**
- 1.10. **Security Deposit:** N/A.
- 1.11. **Sales Taxes.** Tenant shall pay to Landlord with the monthly payment of Rent all applicable sales taxes imposed directly upon such rent or this Lease.
- 1.12. **Number of Parking Spaces:** Up to **twenty seven (27)** total spaces of which **twenty (20)** are unreserved and seven (7) are reserved spaces, all in accordance with the terms of Section 24 hereof.
- 1.13. **Real Estate Brokers:** Landlord: None  
Tenant: None
- 1.14. **Attachments to Lease:** Exhibit A - "Premises"; and Exhibit B - "Rules and Regulations.
- 1.15. **Addresses for Notices:**

**Landlord:** Frost Real Estate Holdings, LLC  
4400 Biscayne Boulevard  
Miami, Florida 33137

**Tenant:** Prior to the Commencement Date: N/A

**After the Commencement Date:**

OPKO HEALTH Inc.,

4400 Biscayne Blvd  
Suites 1580, Annex 1 & 1100,  
Miami, Florida 33137  
Attention: Kate Inman

1.16. **Interpretation.** The Basic Lease Provisions shall be interpreted in conjunction with all of the other terms and conditions of this Lease. Other terms and conditions of this Lease modify and expand on the Basic Lease Provisions. If there is a conflict between the Basic Lease Provisions and the other terms and conditions of this Lease, the other terms and conditions shall control.

## 2. Premises.

**2.1. Lease of Premises.** Landlord hereby leases the Premises to Tenant, together with the right to use any portions of the Project, as hereinafter defined, that are designated by Landlord for the common use of tenants and others (the "Common Areas"). The "Project" consists of the building of which the Premises is a part (the "Building"), the Common Areas, the land upon which the same are located, along with all other buildings and improvements thereon or hereunder, including all parking facilities.

**2.2. Acceptance.** Tenant agrees to accept the Premises in its "as-is" condition existing as of the Commencement Date.

**3. Term.** This Lease shall be in full force and effect from the Effective Date. The Term and Commencement Date of this 611 is 611 this 611

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**8. Insurance.**

**8.1. Insurance-Tenant.** Tenant shall maintain at all times during the Term of this Lease commercial general liability insurance with coverages acceptable to Landlord, which by way of example and not limitation, protects Tenant and Landlord (as an additional insured) against claims for bodily injury, personal injury and property damage based upon, involving or arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto. Such insurance shall be on an occurrence basis providing single limit coverage in an amount of not less than Two Million Dollars (\$2,000,000) per occurrence with an "Additional Insured-Managers and Landlords of Premises Endorsement" and contain the "Amendment of the Pollution Exclusion" for damage caused by heat, smoke or fumes from a hostile fire. The policy shall not contain any intra-insured exclusions as between insured persons or organizations, but shall include coverage for liability assumed under this Lease as an "insured contract" for the performance of Tenant's indemnity obligations under this Lease. If, in the commercially reasonable opinion of the insurance broker retained by Landlord, the amount of public liability or property damage insurance coverage at any time during the Term is not adequate, Tenant shall increase the insurance coverage as required by Landlord. ~~Landlord shall not be liable for any claims or damages arising out of or from the limits of such policy be [redacted] as limiting the liability of Tenant under this Lease.~~

Tenant may also obtain and keep in force during the Term of this Lease "all risk" extended coverage property insurance on Tenant's personal property, all tenant improvements installed at the Premises by Tenant and Tenant's trade fixtures and other property (collectively, "Tenant's Personal Property"). Tenant expressly acknowledges and agrees that in the event its insurance policy fails to cover any of Tenant's Personal Property or excludes coverage for flood, earthquake, wind or fire (including any fire caused by a power outage),





## 12. Assignment and Subletting.

**12.1. Landlord's Consent Required.** Tenant shall not voluntarily or by operation of law assign, transfer, hypothecate, mortgage, sublet, or otherwise transfer or encumber all or any part of Tenant's interest in this Lease or in the Premises (hereinafter collectively a "Transfer"), without Landlord's prior written consent, which consent shall not be unreasonably withheld. Landlord shall respond to Tenant's written request for consent hereunder within fifteen (15) days after Landlord's receipt of the written request from Tenant. Any attempted Transfer without such consent shall be void and shall constitute a default of this Lease. If the entity(ies) which directly or indirectly controls the voting shares/rights of Tenant changes at any time, such change of ownership or control shall constitute a Transfer ~~unless Tenant is an entity whose outstanding stock is listed on a recognized securities exchange or if at least 80% of its voting stock is owned by another entity, the voting stock of which is so listed.~~ Tenant's written request for Landlord's consent shall include all of the following information: (a) financial statements for the proposed assignee or subtenant, (b) a detailed description of the business the assignee or subtenant intends to operate at the Premises, (c) a copy of the fully executed sublease or assignment agreement, and (d) such other information as Landlord may reasonably request.

### 12.2. Stan SU

**12.6. Transfers to Affiliates and Collateral Assignments to Lenders.** Notwithstanding anything to the contrary contained in the Lease, Tenant shall have the right, without Landlord's consent, to assign this Lease or sublet all or any portion of the Premises to: (a) a parent, subsidiary or affiliated entity of Tenant, or (b) any entity to which all or a substantial portion of the assets of Tenant have been transferred, or (c) any entity in connection with a merger, sale of stock, consolidation or other corporate reorganization or transaction involving Tenant (collectively, a "Permitted Transfer"). Tenant shall also have the right to collaterally assign its interest as a tenant in this Lease as security for loan(s) to be made to Tenant (a "Collateral Assignment"). Tenant shall provide Landlord with at least ten (10) business days prior written notice of a Permitted Transfer or a Collateral Assignment.

**13. Default; Remedies.**

**13.1. Default by Tenant.** Landlord and Tenant hereby agree that the occurrence of any one or more of the following events is a default by Tenant under this Lease and that said default shall give Landlord the rights described in Section 13.2. Landlord or Landlord's authorized agent shall have the right to execute and deliver any notice of default, notice to pay rent or quit or any other notice Landlord gives Tenant.



such inability or delay is caused by reason of a Force Majeure Event, and the time for Landlord's performance shall be extended for the period of any such delay. Any claim, demand, right or defense by Tenant that arises out of this Lease or the negotiations which preceded this Lease shall be barred unless Tenant commences an action thereon, or interposes a defense by reason thereof, within one (1) year after the date of the inaction, omission, event or action that gave rise to such claim, demand, right or defense.



**13.4. Late Charges.** If any installment of Rent or any other sum due from Tenant shall not be received by Landlord within five (5) days of when such amount shall be due, then, without any requirement for notice or demand to Tenant, Tenant shall immediately pay to Landlord a late charge equal to five percent (5%) of such overdue amount. The parties hereby agree that such late charge represents a fair and reasonable estimate of the costs Landlord will incur by reason of late payment by Tenant. Acceptance of such late charge by Landlord shall in no event constitute a waiver of Tenant's default with respect to such overdue amount, nor prevent Landlord from exercising any of the other rights and remedies granted hereunder including the assessment of interest under Section 13.5.

**13.5. Interest on Past-due Obligations.** Except as expressly herein provided, any amount due to Landlord that is not paid when due shall bear interest at the lesser of ten percent (10%) per annum, or the maximum rate permitted by applicable law. Payment of such interest shall not excuse or cure any default by Tenant under this Lease; provided, however, that interest shall not be payable on late charges incurred by Tenant nor on any amounts upon which late charges are paid by Tenant.

**13.6. Payment of Rent and Security Deposit After Default.** If Tenant fails to pay Rent or any other monetary obligation due hereunder on the date it is due (taking into account any grace and cure period) on at least three occasions, at Landlord's option, all monetary obligations of Tenant hereunder shall thereafter be paid by cashiers check, and Tenant shall, upon demand, provide Landlord with a Security Deposit equal to three (3) months' Rent. If Landlord has required Tenant to make said payments by cashiers check or to provide an additional Security Deposit, Tenant's failure to make a payment by cashiers check or to provide an additional Security Deposit, shall be a default hereunder.

**14. Landlord's Right to Cure Default; Payments by Tenant.** If Tenant shall fail to perform any of its obligations under this Lease, Landlord shall have the right to make any such payment or perform any such act on Tenant's behalf without waiving its rights based upon any default of Tenant and without releasing Tenant from any obligations hereunder. Tenant shall reimburse Landlord for the cost of such performance upon demand.

**15. Condemnation.** If the Premises or the Project are taken under the power of eminent domain, or sold under the threat of the exercise of said power (all intord

## 17.2. Estoppel Certific





shall in no way affect this Lease or impose any liability upon Landlord.



**28. Signs.** Tenant shall not place any sign upon the Premises (including on the inside or the outside of the doors or windows of the Premises) or the Project without Landlord's prior written consent, which may be given or withheld in Landlord's reasonable discretion. Landlord shall have the right to place any sign it deems appropriate on any portion of the Project except the interior of the Premises. Any sign Landlord permits Tenant to place upon the Premises shall be maintained by Tenant, at Tenant's sole expense. If Landlord permits Tenant to include its name in the Building's directory, the cost of placing Tenant's name in the directory and the cost of any subsequent modifications thereto shall be paid by Tenant, at Tenant's sole expense. Landlord acknowledges and agrees that Tenant shall have the right to place a sign identifying the Premises and a sign identifying that certain of Tenant's principals are the holders of a Florida real estate broker's licenses outside of the Tenant's principal entrance to the Premises with Landlord's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. Landlord further acknowledges that Landlord shall either (i) provide a building directory identifying the Tenant's suite in the lobby of the Building or (ii) advise the Landlord's receptionist seated in the lobby of the Building to direct Tenant's customers and guests to Tenant's suite Dulocena ~ On to

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**30.7. Attorneys' Fees.** If Landlord or Tenant brings an action to enforce the terms hereof or declare rights hereunder, the prevailing party in any such action, or appeal thereon, shall be entitled to its reasonable attorneys' fees and court costs to be paid by the losing party as fixed by the court in the same or separate suit, and whether or not such action is pursued to decision or judgment. The attorneys' fee award shall not be computed in accordance with any court fee schedule, but shall be such as to fully reimburse all attorneys' fees and court costs reasonably incurred in good faith. Landlord shall be entitled to reasonable attorneys' fees and all other costs and expenses incurred in the preparation and service of notices of default and consultations in connection therewith k ůt u i





**30.18 Lease of Furniture.** Landlord hereby also leases )18



- (b) Landlord shall lease to Tenant the Premises in their then current condition, and Landlord shall not provide to Tenant any allowances (e.g., moving allowance, construction allowance, tenant improvements allowance and the like) or other tenant inducements.

Landlord shall deliver written notice (the "Landlord Notice") to Tenant, within thirty (30) days after Landlord's receipt of a timely First Renewal Notice, which sets forth the Rent determined by Landlord to be payable during the First Extension Term after consideration of the factors set forth under clause (a) above. Tenant shall have the right, within ten (10) days following the date of the Landlord Notice, to deliver written notice (the "First Revocation Notice") to Landlord that Tenant elects to revoke its exercise of the renewal option. If Tenant delivers a First Revocation Notice, Tenant shall have no further right to extend the term of this Lease and this Lease shall terminate upon the expiration of the initial term hereof. If Tenant timely delivers a First Renewal Notice but fails to timely deliver a First Revocation Notice, this Lease shall be extended on the terms set forth above and at the Rent specified in the Landlord Notice.

Tenant's right to extend the term of this Lease shall terminate if (i) this Lease or Tenant's right to possession of the Premises is terminated, (ii) Tenant, at any time during the Lease Term, assigns or subleases the Premises to a third party.

WITNESSES:

LANDLORD:

FROST REAL ESTATE HOLDINGS, LLC  
a Florida limited liability company

\_\_\_\_\_  
Print Name: \_\_\_\_\_

By: /s/ Yehuda Ben-Horn

\_\_\_\_\_  
Print Name: \_\_\_\_\_

Name: Yehuda Ben-Horn

Title: VP Engineering Services

TENANT:

OPKO HEALTH INC.,  
a Delaware corporation

\_\_\_\_\_  
Print Name: \_\_\_\_\_

By: /s/ Adam Logal

\_\_\_\_\_  
Print Name: \_\_\_\_\_

Name: Adam Logal

Title: Chief Accounting Officer and Treasurer

OPKO Health, Inc.

CERTIFICATION PURSUANT TO  
RULE 13A-14 OF THE SECURITIES EXCHANGE ACT OF 1934  
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OPKO Health, Inc.  
CERTIFICATION PURSUANT TO  
RULE 13A-14 OF THE SECURITIES EXCHANGE ACT OF 1934  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Rao Uppaluri, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarter ended September 30, 2007 of OPKO Health Inc.;
2. Based on my knowledge, this quarterly 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 quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the period presented in this report. I am not aware of any material misstatements or omissions in these financial statements.
4. The Registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 (e) and 15d-15(e)) 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 the periodic reports are being prepared;

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**Certification Pursuant to Section 906 of the S**

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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 States Code)**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant section 906 of the Sarbanes-Oxley Act of 2002, I, Rao Uppaluri, Chief Financial Officer of OPKO Health, Inc. (the "Company"), hereby certify that:

The Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2007 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2007

/s/ Rao Uppaluri

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Rao Uppaluri  
Chief Financial Officer

A signed original of this written statement required by Section 907 has been provided to the Company and will be

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