Opko Health, Inc.
Form 10-Q
November 14, 2007

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2007.

OR

o **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.
(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) 575-6015
(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, or a nonaccelerated filer (as defined in Rule 12b-2 of the Exchange Act). Check one:

Large accelerated filer o Accelerated filer o Nonaccelerated filer x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): YES o NO x

As of November 9, 2007, the registrant had 163,214,203 shares of common stock outstanding.

2

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, 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 listed below as well as the risks and uncertainties detailed in our Current Report on Form 8-K dated March 27, 2007 and described from time to time in our reports filed with the Securities and Exchange Commission. We intend that all forward-looking statements be subject to the safe-harbor provisions of 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. We do not undertake any obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

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 research and development activities may not result in commercially viable products.
- 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.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.
- 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.

- Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our products.

- If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

- As we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

- If we fail to acquire and develop other products or product candidates at all or on commercially reasonable terms, we may be unable to diversify or grow our business.

- We currently have a limited marketing staff amd sales and 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 product candidates.

- 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 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.

- Acquisitions may disrupt our business, distract our management and may not proceed as planned, and we may encounter difficulty in integrating acquired businesses into our operations.

Item 1. Financial Statements:

Our results of operations for the first nine months of 2007 include Froptix' operating results for the full nine month period and Acuity's operating results subsequent to March 27, 2007. As a result of the reverse merger between Froptix and eXegenics, historical comparative results are those of Froptix. Froptix was incorporated on June 23, 2006 and did not have significant operations for most of the period from inception (June 23, 2006) through September 30, 2006. Refer to Note 1.

OPKO Health, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(A Development Stage Company)
(in thousands except share data)
(unaudited)

	September 30, 2007	December 31, 2006
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,670	$ 116
Prepaid expenses and other current assets	1,018	—
Total current assets	5,688	116
Property and equipment, net	275	—
Investment in Ophthalmic Technologies, Inc. (OTI)	4,874	—
Other assets	22	—
Total assets	$ 10,859	$ 116
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable, net unamortized discount of $56 and capital lease obligations	$ 3,319	$ —
Accounts payable	1,349	95
Accrued expenses	1,741	—
Total current liabilities	6,409	95
Line of credit with a related party, net of unamortized discount of $371	7,629	—
Long-term capital lease obligations	9	—
Total liabilities	14,047	95
Commitments and contingencies		
Shareholders' (deficit) equity:		
Series A Preferred stock — $0.01 par value, 4,000,000 shares authorized; 869,366 and 0 shares issued and outstanding (liquidation value of $2,336 and $0) at September 30, 2007 and December 31, 2006, respectively	9	—
Series C Preferred Stock $0.01 par value, 500,000 shares authorized; no shares issued or outstanding	—	—
Common stock — $0.01 par value, 500,000,000 shares authorized; 163,192,608 and 61,775,002 shares issued and outstanding, respectively	1,632	618
Additional paid-in capital	255,639	280
Deficit accumulated during development stage	(260,468)	(877)
Total shareholders' (deficit) equity	(3,188)	21
Total liabilities and shareholders' (deficit) equity	$ 10,859	$ 116

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

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

	Three Months Ended September 30, 2007	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2007	Period From Inception (June 23, 2006) to September 30, 2006	Cumulative Period From Inception (June 23, 2006) to September 30, 2007
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses (reversal):					
Selling, general and administrative	2,722	9	8,151	9	8,526
Research and development	(4,496)	1	7,010	251	7,519
Write-off of acquired in-process research and development	—	—	243,761	—	243,761
Total operating expenses (reversal)	(1,774)	10	258,922	260	259,806
Operating income (loss)	1,774	(10)	(258,922)	(260)	(259,806)
Other (expense) income, net	(202)	3	(379)	3	(372)
Income (loss) before income taxes and investment loss from OTI	1,572	(7)	(259,301)	(257)	(260,178)
Income taxes	—	—	—	—	—
Net income (loss) before investment loss from OTI	1,572	(7)	(259,301)	(257)	(260,178)
Loss from investment in OTI	(91)	—	(126)	—	(126)
Net income (loss)	1,481	(7)	(259,427)	(257)	(260,304)
Preferred stock dividend	(41)	—	(164)	—	(164)
Net income (loss) attributable to common shareholders	$ 1,440	$ (7)	$ (259,591)	$ (257)	$ (260,468)
Income (loss) per share, basic	$ 0.01	$ (0.00)	$ (2.24)	$ (0.01)	
Income (loss) per share, diluted	$ 0.01	$ (0.00)	$ (2.24)	$ (0.01)	

Weighted average number of shares outstanding - basic	162,793,526	51,731,927	116,034,500	47,593,373
Weighted average number of shares outstanding - diluted	205,149,747	51,731,927	116,034,500	47,593,373

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

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)

	Series A Preferred Stock		Series C Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Dollars	Shares	Dollars	Shares	Dollars	Capital	Deficit	Tota
Issuance of capital stock to founders of Froptix, $0.01 per share	—	$ —	—	$ —	61,775,002	$ 618	$ 20	$ —	6
Stock-based compensation expense	—	—	—	—	—	—	260	—	2
Net loss for the period from inception (June 23, 2006) to December 31, 2006	—	—	—	—	—	—	—	(877)	(8
Balance at December 31, 2006	—	—	—	—	61,775,002	618	280	(877)	
Stock-based compensation expense	—	—	—	—	—	—	5,684	—	5,6
Issuance of common and preferred stock and options and warrants for net monetary assets at $0.43 per share	1,081,750	11	—	—	36,607,023	366	15,626	—	16,0
Issuance of equity securities to acquire Acuity Pharmaceuticals, Inc. at $2.65 per share	—	—	457,584	5	14,778,997	148	234,470	—	234,6
Issuance of common stock upon automatic conversion of Series C preferred stock	—	—	(457,584)	(5)	45,758,400	457	(452)	—	

Exercise of stock options	—	—	—	—	343,062	4	68	—	
Exercise of common warrants	—	—	—	—	3,717,740	37	(37)	—	
Conversion of Series A preferred stock	(212,384)	(2)	—	—	212,384	2	—	—	
Preferred stock dividend	—	—	—	—	—	—	—	(164)	(1
Net loss for the nine months ended September 30, 2007	—	—	—	—	—	—	—	(259,427)	(259,4
Balance at September 30, 2007	869,366	$ 9	—$	—	163,192,608	$ 1,632	$ 255,639	$ (260,468)	$ (3,1

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

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

	Nine Months Ended September 30, 2007	Period from inception (June 23, 2006) to September 30, 2006	Cumulative period from inception (June 23, 2006) to September 30, 2007
Cash flows from operating activities:			
Net loss	$ (259,427)	$ (257)	$ (260,304)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	17	—	17
Write-off of in-process research and development	243,761	—	243,761
Amortization of debt discount related to notes payable	154	—	154
Loss from investment in OTI	126	—	126
Stock compensation — employees and vendors	5,684	1	5,943
Changes in:			
Prepaid expenses and other current assets	(431)	(39)	(431)
Other assets	(22)		(22)
Accounts payable	(720)	8	(625)
Accrued expenses	(236)	—	(236)
Net cash used in operating activities	(11,094)	(287)	(11,617)
Cash flows from investing activities:			
Investment in OTI	(5,000)	—	(5,000)
Acquisition of a business, net of cash	1,135	—	1,135
Capital expenditures	(208)	—	(208)
Net cash used in investing activities	(4,073)	—	(4,073)
Cash flows from financing activities:			
Issuance of common stock for cash	—	639	639
Proceeds from stock option exercises	72	—	72
Borrowings under line of credit with related party	4,000	—	4,000
Repayments of notes payable and capital lease obligations	(635)	—	(635)
Proceeds from sale of common stock, net	16,284	—	16,284
Net cash provided by financing activities	19,721	639	20,360
Net change in cash	4,554	352	4,670
Cash and cash equivalents at beginning of period	116	—	—
Cash and cash equivalents at end of period	$ 4,670	$ 352	$ 4,670

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

OPKO Health, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(A Development-Stage Company)

Note 1 Business and Organization

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 continue to seek 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 are a Delaware corporation, headquartered in Miami, Florida with clinical operations in Morristown, New Jersey.

On February 9, 2007, *eXegenics, Inc.* completed the sale of 19,440,491 shares of its common stock for $8.0 million, constituting 51% of its issued and outstanding shares of capital stock on a fully diluted basis, to a small group of investors led by The Frost Group, LLC, or the Frost Group, a related party. On March 27, 2007, pursuant to the terms of a Merger Agreement and Plan of Reorganization, Froptix Corporation, or Froptix, a development stage research and development company, controlled by the Frost Group, and Acuity Pharmaceuticals, Inc., or Acuity, a development stage research and development company and *eXegenics* were part of a three-way merger. Per that agreement, *eXegenics* issued new capital stock to acquire all of the issued and outstanding capital stock of Froptix and Acuity. On June 8, 2007, we changed our name to OPKO Health, Inc., from *eXegenics,* Inc. Through March 26, 2007, *eXegenics* was a public shell company whose assets consisted of cash and nominal other assets.

Froptix was the accounting acquirer in the three-way merger referenced above. The three-way merger has been accounted for as:

- a reverse merger between Froptix and *eXegenics* (a public shell company). For accounting purposes Froptix has been treated as the continuing registrant. As a result, all post merger comparative historical financials statements filed by us will be those of Froptix. Froptix was incorporated on June 23, 2006. Further, Froptix' historical shareholders' equity prior to the merger has been retroactively restated (recapitalized) for the equivalent number of shares received in the reverse merger. Earnings and loss per share calculations have also been retroactively restated to give effect to the recapitalization for all periods presented. Lastly, the merger between Froptix and *eXegenics* has been accounted for as a capital transaction equivalent to the issuance of capital stock by Froptix for the net monetary assets of *eXegenics*.

- an asset acquisition of Acuity by Froptix.

The Merger Agreement provided for the merger of Froptix with and into e-Acquisition Company I-A, LLC, with e-Acquisition Company I-A, LLC surviving as our wholly-owned subsidiary (referred to as the "Froptix Merger") and the merger of Acuity with and into e-Acquisition Company II-B, LLC, with e-Acquisition Company II-B, LLC surviving as our wholly-owned subsidiary (referred to as the "Acuity Merger" and, with the Froptix Merger, the "Mergers"). In connection with the consummation of the Mergers (1) e-Acquisition Company I-A, LLC changed its name to Froptix, LLC, (2) e-Acquisition Company II-B, LLC changed its name to Acuity Pharmaceuticals, LLC and again changed its name to OPKO Ophthalmologics, LLC and (3) OPKO became the parent company of these two wholly-owned operating subsidiaries. At the closing of the Mergers, the former shareholders of Froptix and Acuity

received shares of our common stock and preferred stock as well as warrants to purchase our common stock in exchange for all of their shares of Froptix and Acuity.

As a result, at the closing of the Mergers, we issued (a) an aggregate of 61,775,002 shares of our common stock to the former holders of Froptix common stock, (b) an aggregate of 14,778,997 shares of our common stock to the former holders of Acuity common stock and Acuity Series A preferred stock, and (c) an aggregate of 457,584 shares of our Series C preferred stock, convertible into 45,758,400 shares of our common stock, to the former holders of Acuity Series B preferred stock. We also granted 21,144,128 warrants to purchase shares of our common stock to former shareholders of Froptix and Acuity and 15,810,131 options to purchase our common stock to former option holders of Froptix and Acuity. All of the options granted the former holder of the Froptix options were cancelled during the third quarter of 2007.

Acuity Asset Acquisition. 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 two days prior to the transaction.

The following table summarizes the estimated fair value of the net assets acquired at the date of acquisition:

(in thousands)		
Current assets (including cash of $1,135)	$	1,350
Property and equipment		85
In-process research and development		243,761
Accounts payable and accrued expenses		(3,154)
Line of credit and term loan		(7,419)
Total purchase price	$	234,623

The portion of the purchase price allocated to in-process research and development of $243.8 million was immediately expensed. The purchase price includes $1.5 million of costs incurred by *eXegenics* to acquire Acuity, including $1.3 million of costs associated with the issuance of warrants to the Frost Group as a result of the increase of the credit line with Acuity. Refer to Note 4. The purchase consideration issued and the purchase price allocation are preliminary pending completion and review of related valuation procedures. As a result the amounts above are subject to change.

Treatment of Warrants and Options. In connection with the Mergers, we assumed the obligations under outstanding warrants previously granted by Acuity to purchase 1,247,271 shares of Acuity common stock and 325,000 shares of Acuity Series B preferred stock and, in connection therewith, we issued warrants to purchase 7,214,730 shares of our common stock and warrants to purchase 16,866 shares of Series C preferred stock to such Acuity warrant holders, convertible into 1,686,600 shares of our common stock.

Immediately before the closing of the Mergers, Froptix had outstanding options to purchase 65 shares of Froptix common stock and Acuity had outstanding options to purchase 2,191,619 shares of Acuity common stock and options to purchase 141,000 shares of Acuity Series B preferred stock. Pursuant to the terms of the Merger Agreement, the Company assumed all of the outstanding obligations under such options and, accordingly, the Company anticipates issuing 15,810,131 shares of its common stock and 7,317 shares of its Series C preferred stock, convertible into 731,700 shares of our common stock, upon the exercise of such options in lieu of shares of common stock of Froptix or common stock and/or preferred shares of Acuity.

The following table includes the pro forma results for the three months ended September 30, 2006 of the combined companies as though the acquisition of Acuity had been completed as of June 23, 2006.

(in thousands, except per share amounts)	**As reported**	**Pro forma adjustments**	**Pro forma**
Revenue	$ —	$ —	$ —
Net loss	$ (7)	$ (2,276)	$ (2,283)
Basic and diluted loss per share	$ (0.00)	$ (0.03)	$ (0.03)

The following table includes the pro forma results for the period from inception (June 23, 2006) to September 30, 2006 of the combined companies as though the Mergers had been completed as of June 23, 2006.

(in thousands, except per share amounts)	As reported	Pro forma adjustments	Pro forma
Revenue	$ —	$ —	$ —
Net loss	$ (257)	$ (2,519)	$ (2,776)
Basic and diluted loss per share	$ (0.01)	$ (0.04)	$ (0.04)

The following table includes the pro forma results for the nine months ended September 30, 2007 of the combined companies as though the Mergers had been completed as of January 1, 2007.

(in thousands, except per share amounts)	As reported	Pro forma adjustments	Pro forma
Revenue	$ —	$ —	$ —
Net loss	$ (259,591)	$ (6,792)	$ (266,383)
Basic and diluted loss per share	$ (2.24)	$ (0.05)	$ (2.12)

On January 11, 2007, the Frost Group extended a $7.0 million line of credit to Acuity. As part of the merger transaction on March 27, 2007, the Frost Group increased its line of credit to Acuity to $12 million and consented to the transfer of Acuity's repayment obligation to OPKO.

Note 2 Development Stage Risks and Liquidity

We have been in the development stage since inception and have not generated any revenues. We have not achieved profitable operations and we expect to incur substantial losses in future periods. Accordingly, the accompanying financial statements have been prepared using the accounting formats prescribed by SFAS No. 7 "Accounting and Reporting by Development Stage Enterprises." The successful completion of our development program and our transition to commercial operations, if at all, is dependent upon obtaining necessary regulatory approvals from the United States Food and Drug Administration ("FDA") prior to selling our products within the United States, and foreign regulatory approvals must be obtained to sell our products internationally. There can be no assurance that our products will receive regulatory approvals, and a substantial amount of time may pass before we achieve a level of sales adequate to support our operations, if at all. We will also incur substantial expenditures in connection with the development and regulatory approval process for our products and we will need to raise significant additional capital during the developmental period. Obtaining marketing approval will be directly dependent on our ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and other countries and the success of our clinical trials. We cannot predict the outcome of these activities. Additionally, there is no assurance that profitable operations, if ever achieved, could be sustained on a continuing basis. In addition, development activities and clinical and preclinical testing and commercialization of our proprietary technology will require significant additional financing. Our deficit accumulated during the development stage through September 30, 2007 was $260.5 million, and we expect to incur substantial losses in future periods.

Our future operations are dependent on the timely and successful completion of our ongoing research and development, the development of competitive therapies by other biotechnology and pharmaceutical companies, other treatment modalities for our targeted diseases, and ultimately, regulatory approval and market acceptance of our proposed future products.

The cash and cash equivalents on hand and our available credit line at September 30, 2007 will not be sufficient to meet our anticipated cash requirements for operations and debt service for at least the next 12 months and we will require additional funding during the first half of 2008. We intend to finance future operations with a combination of

private placements; payments from potential strategic research and development, licensing and/or marketing arrangements; public offerings; debt financing; and revenues from future product sales, if any. We have not generated positive cash flows from operations, and there are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our planned products. Our ability to continue as a going concern is dependent upon the infusion of addition capital in the future and there is no assurance that additional capital will be available to the Company on acceptable terms, or at all.

Note 3 Summary of Significant Accounting Policies

Basis of Presentation. The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. 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.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents. 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. 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.

Impairment of Long-Lived Assets. In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*, 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 Development. Research and product development costs are charged to expense as incurred. We record expense for in-process research and development as those that had not reached technological feasibility and which had no alternative use.

Income Taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

Loss Per Common Share. Basic and diluted earnings or loss per common share is based on the net loss increased by dividends on preferred stock divided by the weighted average number of common shares outstanding during the period. In the periods in which their effect would be anti-dilutive, no effect has been given to outstanding options,

warrants or convertible preferred stock in the diluted computation. As of September 30, 2007, we have 163,192,608 common shares outstanding, in addition, we have options, warrants and convertible preferred stock outstanding at September 30, 2007 that, if converted or exercised would result in 46,364,091 incremental shares of common stock being outstanding resulting in 209,556,699 potential common shares outstanding. The year to date diluted loss per share does not include the weighted average impact of the outstanding option and warrants of 4,944,296 for the nine months ended September 30, 2007 because their inclusion would have been anti-dilutive.

Share-Based Compensation. We follow the provisions of Financial Accounting Standards Board ("FASB") Statement of Financial Accounting Standards ("Statement") No. 123 (revised 2004), *Share-Based Payment* ("SFAS 123R"), which requires that a company measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the statement of operations over the period during which an employee is required to provide service in exchange for the award. SFAS 123R also requires that excess tax benefits, as defined, realized from the exercise of stock options be reported as a financing cash inflow rather than as a reduction of taxes paid in cash flow from operations. Refer to Note 5. Stock-based compensation arrangements to non-employees are accounted for in accordance with SFAS No. 123R and Emerging Issues Task Force Issue No. 96-18 (EITF 96-18), "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," which requires that these equity instruments are recorded at their fair value on the measurement date. The measurement of stock-based compensation is subject to periodic adjustment as the underlying equity instruments vest.

Comprehensive income or loss. Our comprehensive income or loss has no components other than net income or loss for all periods presented.

New accounting pronouncements: In July 2006, the Financial Accounting Standards Board, or FASB, issued Interpretation Number, or FIN, No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48. FIN 48 applies to all tax positions within the scope of SFAS No. 109, applies a "more likely than not" threshold for tax benefit recognition, identifies a defined methodology for measuring benefits and increases the disclosure requirements for companies. FIN 48 is mandatory for years beginning after December 15, 2006; accordingly, we have adopted FIN 48 effective January 1, 2007. Refer to Note 6.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and expands disclosures about fair value measurements. This Statement applies to other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. SFAS No. 157 is effective for fiscal years beginning after December 15, 2007. We plan to adopt SFAS No. 157 beginning in the first quarter of our 2008 fiscal year. We are currently evaluating the impact the adoption of SFAS No. 157 may have on our financial position and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS No. 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 No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the impact the adoption of SFAS No. 159 may have on our financial position and the results of operations.

In June 2007, the Emerging Issues Task Force, or EITF, issued EITF 07-3 *Accounting for Advance Payments for Goods or Services to be Received for Use in Future Research and Development Activities*. This EITF establishes that prepayments made related to research and development goods and services should be capitalized and recognized as expense when the goods are received or the services have been performed. The prepaid assets must be assessed for recoverability to ensure the prepaid goods or services will continue to be used. EITF 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We are currently evaluating the impact the adoption of EITF 07-3 may have on our financial position and the results of operations.

13

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 *eXegenics* ($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 2007. Principal on the term loan matures as follows: $1.7 million during 2007 and which $0.6 million has been repaid through September 30, 2007 and $2.3 million during 2008. The term loan is collateralized by all personal property of Acuity, except intellectual property, and contains certain negative covenants that limit the payment of cash dividends, redemption of equity securities, changes in ownership, and the creation or extinguishment of debt. In connection with the issuance of the term note, Acuity issued warrants to purchase 200,000 shares of Series B preferred stock at $2.00 per share, which upon the Mergers converted to 10,379 shares of our Series C preferred stock and warrants to purchase 25,000 shares of common stock at $0.01 per share, which converted to 129,736 shares of our common stock upon consummation of the Merger. On June 22, 2007, the Series C preferred stock automatically converted to 1,037,900 shares of our common stock.

Note 5 Stock-Based Compensation

As of September 30, 2007, we had three stock-based compensation plans, our 1996 Stock Option Plan, our 2000 Stock Option Plan and our 2007 Equity Incentive Plan. We also assumed the option plans of Acuity and Froptix in the merger discussed in Note 1 (collectively the "Plans"). Options granted under the 1996 Stock Option Plan, 2000 Stock Option Plan and the plans assumed from Froptix and Acuity are exercisable for a period of up to 10 years from date of grant. Options granted under the 2007 Equity Incentive Plan are exercisable for a period up to 7 years. Vesting periods range from immediate to 4 years. The compensation expense recognized in the statements of operations for the three and nine months ended September 30, 2007 for our stock-based compensation plans was a reversal of expense of

$6.3 million and an accrual of $5.7 million, respectively. During the three and nine months ended September 30, 2007, $0.7 million and $3.4 million was included as a component of general and administrative expenses, respectively. The three and nine months ended September 30 also included a reversal of $7.0 million and an expense of $2.3 million were classified as a component of research and development expenses, respectively.

The fair value of the unvested Acuity option awards was determined at the Merger date and will be expensed over the remaining requisite service period of the options. Unvested options granted to non-employees are marked to market each reporting period in accordance with EITF 96-18. The fair value of stock option awards was estimated using the Black-Scholes option valuation model and the assumptions noted in the following table:

	Three Months Ended September 30, 2007	Nine Months Ended September 30, 2007
Expected life	4.00 to 9.42 years	3.48 to 9.72 years
Expected volatility	73%	73% to 76%
Risk-free interest rate	4.00% to 5.10%	4.00% to 5.16%
Dividend yield	0%	0%

The expected life of the stock options was calculated using the shortcut method allowed by the provisions of SFAS No. 123R and interpreted by Staff Accounting Bulletin No. 107 (SAB 107). The expected volatility was based on a peer group of publicly-traded stock which we believe will be representative of the volatility over the expected term of the options. The risk-free interest rate is based on the rates paid on securities issued by the U.S. Treasury with a term approximating the expected life of the option. The dividend yield is based on the projected annual dividend payment per share, divided by the stock price at the date of grant; however, we have not, and do not expect to declare such dividends.

A summary of the stock option activity under our Plans during the nine months ended September 30, 2007 is presented below:

	Shares	Exercise price per share	Weighted average exercise price
Outstanding at December 31, 2006	4,436,878	$ 0.01	$ 0.01
Assumed from *eXegenics* at merger	305,000	0.32 - 0.89	0.64
Assumed from Acuity at merger	11,373,253	0.04 - 0.56	0.14
Cancelled/Forfeited	(19,785)	0.05 - 0.06	0.05
Outstanding at March 31, 2007	16,095,346	0.01 - 0.89	0.11
Granted	3,845,000	3.54 - 4.88	4.81
Exercised	(79,215)	0.05 - 0.84	0.80
Canceled/Forfeited	(525,811)	0.04 - 0.06	0.05
Outstanding at June 30, 2007	19,335,320	$ 0.01 - $4.88	$ 1.04
Granted	270,000	3.80 - 4.87	4.09
Exercised	(276,136)	0.04 - 1.67	0.21
Canceled/Forfeited	(4,504,743)	0.01 - 4.88	0.02
Outstanding at September 30, 2007	14,824,441	$ 0.04 - $4.88	$ 1.42

As of September 30, 2007 there was approximately $15.8 million of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a remaining weighted-average vesting period of 3.1 years. As of September 30, 2007, approximately 8.0 million options to purchase our common stock were exercisable. In addition, at September 30, 2007, 11.0 million outstanding options were in the money with an aggregate intrinsic value of approximately $42.0 million.

In addition to the common stock options there were 7,317 options to purchase Series C preferred stock at an exercise price of $32.00 issued as replacement options to an Acuity employee at the Merger, which, upon conversion of the Series C Preferred stock on June 22, 2007 converted to 731,700 options to purchase our common stock. The common stock options were 100% vested and exercisable as of September 30, 2007. The intrinsic value of the options on September 30, 2007 was $3.0 million.

On May 11, 2007, we entered into a Settlement Agreement with our former President. Under the terms of the Settlement Agreement, our former President will receive a severance payment equivalent to one year's salary of $325,000, paid monthly, and reimbursement of up to $65,000 in relocation expenses. In addition, all outstanding equity awards which would have vested by May 31, 2008, were automatically vested. As a result of this acceleration, during the second quarter of 2007 we recorded $1.5 million of additional compensation expense that would have been recognized over the period from June 1, 2007 through May 31, 2008.

In July 2007, we terminated a consulting agreement prior to the vesting of approximately 4.4 million options to purchase our common stock. As a result, during the third quarter of 2007, we reversed compensation expense, included in research and development which was accrued during the previous 12 months of approximately $8.1 million.

Note 6 Income Taxes

Prior to January 1, 2007, we recognized income taxes with respect to uncertain tax positions based upon SFAS No. 5, "*Accounting for Contingencies"*, or SFAS No. 5. Under SFAS No. 5, we would record a liability associated with an uncertain tax position if the liability was both probable and estimable. Prior to January 1, 2007, the liabilities recorded under SFAS No. 5 including interest and penalties related to income tax exposures, would have been recognized as incurred within "income taxes" in our condensed consolidated statements of operations. We recorded no such liabilities in 2006.

Effective January 1, 2007, we adopted FIN 48, "*Accounting for Uncertainty in Income Taxes*." FIN 48 clarifies the accounting for uncertainty in income taxes recognized in financial statements in accordance with SFAS No. 109, "*Accounting for Income Taxes*." FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 requires that we determine whether the benefit of our tax positions are more likely than not to be sustained upon audit, based on the technical merits of the tax position. For tax positions that are more likely than not to be sustained upon audit, we recognize the greatest amount of the benefit that is more likely than not to be sustained in our condensed consolidated financial statements. For tax positions that are not more likely than not to be sustained upon audit, we do not recognize any portion of the benefit in our condensed consolidated financial statements. The provisions of FIN 48 also provide guidance on derecognition, classification, interest and penalties, accounting in interim periods, and disclosure.

Our policy for interest and penalties under FIN 48, related to income tax exposures, was not impacted as a result of the adoption of the recognition and measurement provisions of FIN 48. Therefore, we continue to recognize interest and penalties as incurred within "*income taxes*" in our condensed consolidated statements of operations, when applicable.

There was no change to our accumulated deficit as of January 1, 2007 as a result of the adoption of the recognition and measurement provisions of FIN 48.

Uncertain Income Tax Positions

We file income tax returns in the U.S. federal jurisdiction and with various states. We are subject to tax audits in all jurisdictions for which we file tax returns. Tax audits by their very nature are often complex and can require several years to complete. There are currently no tax audits that have commenced with respect to income returns in any jurisdiction.

Federal: Under the tax statute of limitations applicable to the Internal Revenue Code, we are no longer subject to U.S. federal income tax examinations by the Internal Revenue Service for years before 2003. However, because we are carrying forward income tax attributes, such as net operating losses and tax credits from 2002 and earlier tax years,

these attributes can still be audited when utilized on returns filed in the future.

State: Under the statutes of limitation applicable to most state income tax laws, we are no longer subject to state income tax examinations by tax authorities for years before 2003 in states in which we have filed income tax returns. Certain states may take the position that we are subject to income tax in such states even though we have not filed income tax returns in such states and, depending on the varying state income tax statutes and administrative practices, the statute of limitations in such states may extend to years before 2003.

As a result of our January 1, 2007 implementation of FIN 48, the total amount of gross tax benefits, excluding the offsetting full valuation allowance, that became unrecognized, was approximately $0.3 million. There were no accrued interest and penalties resulting from such unrecognized tax benefits. As of September 30, 2007, the total amount of gross unrecognized tax benefits was approximately $0.3 million, and accrued interest and penalties on such unrecognized tax benefits was $0.

The net unrecognized tax benefits that, if recognized, would impact the effective tax rate as of September 30, 2007 and December 31, 2006, were $0 and $0, respectively.

We do not anticipate that any significant increase or decrease to the gross unrecognized tax benefits will be recorded during the remainder of 2007.

Other Income Tax Disclosures

Consistent with 2006, we anticipate recording a full valuation allowance against all of our deferred tax assets during 2007. As a result of this valuation allowance, we expect our full year effective tax rate to be at or about zero.

Under Section 382 of the Internal Revenue Code, certain significant changes in ownership may restrict the future utilization of our tax loss carryforwards. The annual limitation is equal to the value of our stock immediately before the ownership change, multiplied by the long-term tax-exempt rate (i.e., the highest of the adjusted federal long-term rates in effect for any month in the three-calendar-month period ending with the calendar month in which the change date occurs). We are undergoing a study to determine whether we or any of our predecessors have undergone an ownership change under Section 382. It is possible that such a study could conclude that some or all of our net operating loss and credit carryforwards will be limited to utilization. Because we currently have recorded full valuation allowances against such tax attributes, we do not expect the results of such a study to have a material impact on our financial statements.

Note 7 Supplemental Cash Flow Information

Supplemental cash flow information is summarized as follows:

(in thousands)	Nine Months Ended September 30, 2007	Period from June 23, 2006 (inception) to September 30, 2007
Interest paid	$ 245	$ 245

Note 8 Related Party Transactions

In June 2007, we paid the $125,000 filing fee payable to the Federal Trade Commission in connection with filings to be made by us and Dr. Frost, our Chairman and Chief Executive Officer, under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (“HSR”). The filings permit Dr. Frost and his affiliates to acquire additional voting securities upon expiration of the HSR waiting period which expired on July 12, 2007.

In November 2007, we entered into an office lease with Frost Real Estate Holdings, LLC, an entity affiliated with Dr. Phillip Frost, the Company's Chairman of the Board and Chief Executive Officer. The Lease is for approximately 8,300 square feet of space in an office building in Miami, Florida, where the Company's principal executive offices are located. We had previously been leasing this space from Frost Real Estate Holdings on a month-to-month basis while the parties were negotiating the lease. The Lease provides for payments of approximately $18,000 per month in

the first year increasing annually to $24,000 per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking. The rent for the first year has been reduced to reflect a $30,000 credit for the costs of tenant improvements.

As part of the Mergers, we assumed a line of credit with the Frost Group from Acuity. Refer to Note 4.

Note 9 Commitments and Contingencies

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.

We have received notice of an action pursuant to which one of our warrant holders is demanding that the Company issue warrants to purchase 259,472 shares of our common stock at $0.0019 per share pursuant to the terms of a warrant agreement with Acuity Pharmaceuticals (the “Warrant”). We are currently evaluating what number, if any, additional warrants are required to issue to the warrant holder based on the terms of the Warrant. We currently estimate that the number of warrants we may be required to issue ranges from 0 to 259,472, but we are unable to reasonably estimate the amount of the potential liability, if any, within this range of estimates.

Note 10 Description of Equity Securities

Our authorized capital stock consists of 500,000,000 shares of common stock, par value $.01 per share, and 10,000,000 shares of preferred stock, par value $.01 per share.

Common Stock

Of the authorized common stock, 163,214,203 shares were outstanding as of November 9, 2007 and are held by approximately 406 record holders. Subject to the prior rights of the holders of any shares of preferred stock currently outstanding or which may be issued in the future, the holders of the common stock are entitled to receive dividends from our funds legally available therefore when, as and if declared by our board of directors, and are entitled to share ratably in all of our assets available for distribution to holders of common stock upon the liquidation, dissolution or winding-up of our affairs subject to the liquidation preference, if any, of any then outstanding shares of preferred stock. Holders of our common stock do not have any preemptive, subscription, redemption or conversion rights. Holders of our common stock are entitled to one vote per share on all matters which they are entitled to vote upon at meetings of stockholders or upon actions taken by written consent pursuant to Delaware corporate law. The holders of our common stock do not have cumulative voting rights, which means that the holders of a plurality of the outstanding shares can elect all of our directors. All of the shares of our common stock currently issued and outstanding are fully-paid and nonassessable. No dividends have been paid to holders of our common stock since our incorporation, and no cash dividends are anticipated to be declared or paid in the reasonably foreseeable future.

Preferred Stock

Our board of directors has the authority, without further action by the holders of the outstanding common stock, to issue preferred stock from time to time in one or more classes or series, to fix the number of shares constituting any class or series and the stated value thereof, if different from the par value, as to fix the terms of any such series or class, including dividend rights, dividend rates, conversion or exchange rights, voting rights, rights and terms of redemption (including sinking fund provisions), the redemption price and the liquidation preference of such class or series. We presently have one series of preferred stock outstanding, designated as Series A convertible preferred stock (the “Series A preferred stock”). We have no present plans to issue any other series or class of preferred stock. The designations, rights and preferences of the Series A preferred stock are set forth in the certificate of designations of Series A convertible preferred stock, which has been filed with the Secretary of State of the State of Delaware.

Series A Preferred Stock

Of the authorized preferred stock, 4,000,000 shares have been designated Series A preferred stock, 869,366 of which are currently issued and outstanding and held by 60 stockholders as of November 9, 2007. Dividends are payable on the Series A preferred stock in the amount of $.25 per share, payable annually in arrears. At the option of our board of directors, dividends will be paid either (i) wholly or partially in cash or (ii) in newly issued shares of Series A preferred stock valued at $2.50 per share to the extent cash dividend is not paid.

Holders of Series A preferred stock have the right to convert their shares, at their option exercisable at any time, into shares of our common stock on a one-for-one basis subject to anti-dilution adjustments. These anti-dilution adjustments are triggered in the event of any subdivision or combination of our outstanding common stock, any payment by us of a stock dividend to holders of our common stock or other occurrences specified in the certificate of designations relating to the Series A preferred stock. We may elect to convert the Series A preferred stock into common stock or a substantially equivalent preferred stock in the case of a merger or consolidation in which we do not survive, a sale of all or substantially all of our assets or a substantial reorganization of us.

Each share of Series A preferred stock is entitled to one vote on all matters on which the common stock has the right to vote. Holders of Series A preferred stock are also entitled to vote as a separate class on any proposed adverse change in the rights, preferences or privileges of the Series A preferred stock and any increase in the number of authorized shares of Series A preferred stock. In the event of any liquidation or winding up of the Company, the holders of the Series A preferred stock will be entitled to receive $2.50 per share plus any accrued and unpaid dividends before any distribution to the holders of the common stock and any other class of series of preferred stock ranking junior to it.

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:

- *Preferred Stock*. 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.

- *Election and Removal of Directors*. 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.

- *Stockholder Meetings*. 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.

- *Requirements for Advance Notification of Stockholder Nominations and Proposals*. Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee thereof.

Note 11 Acquisition

On April 13, 2007, pursuant to a definitive Share Purchase Agreement (the "Purchase Agreement"), we invested $5.0 million in Ophthalmic Technologies, Inc., or OTI, an Ontario corporation for one-third of OTI's share capital on a fully diluted basis and 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 currently negotiating definitive transaction documents relating to the acquisition.

We have accounted for the investment in OTI under the equity method of accounting. The initial $5 million investment was allocated between the investment in OTI and the option to purchase the remainder of OTI. The option was valued based on the estimated exercise price of the option and the estimated market value of the outstanding shares of OTI. The table below reconciles the investment in OTI:

(in thousands)	**Initial investment**	**(Decrease) during the investment period**	**Balance at September 30, 2007**
Option to purchase remaining shares of OTI	$ 618	$ —	$ 618
Investment in OTI	4,382	(126)	4,256
Total	$ 5,000	$ (126)	$ 4,874

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 Current Report on Form 8-K dated March 27, 2007 (the " Form 8-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 this report. 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, 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 *eXegenics*, Inc., or *eXegenics*. On March 27, 2007, we were part of a three-way merger between Froptix Corporation, or Froptix, a research and development company, *eXegenics*, 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 Froptix and *eXegenics*, with the combined company then acquiring Acuity. *eXegenics*, 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, *eXegenics* 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.

21

RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2007 AND 2006

The results of operations for the three months ended September 30, 2007 include the operating results for the full three month period. As a result of the reverse merger, historical comparative results are those of Froptix only.

Selling, General and Administrative Expense. General and administrative expense for the three months ended September 30, 2007 was $2.7 million compared to $9,000 of expense for the comparable period of 2006. General and administrative expense primarily included personnel costs, including stock-based compensation and professional fees. During 2007, we anticipate general and administrative expense to increase to reflect the increased costs of being an operating public company. We incurred costs related to building a commercial infrastructure during the three months ended September 30, 2007 in preparation of completing the acquisition of OTI and anticipate incurring additional costs throughout the remainder of 2007. We were formed on June 23, 2006 and as a result, did not incur significant expenses during the comparable period of 2006.

Research and Development Expense. Research and development expense for the three months ended September 30, 2007 includes a reversal of $8.1 million of equity based compensation expense as a result of the termination of a consulting agreement. Under SFAS 123R, when an equity based compensation award is forfeited prior to vesting, all compensation expense recorded in previous periods is reversed in the period of forfeiture. As a result, research and development expense in the three month period ended September 30, 2007 reflects this reversal and is an offset to expense of $4.5 million. Research and development expenses primarily related to personnel costs, including stock-based compensation as well as costs related to the initiation of our Phase III clinical trial for bevasiranib in July 2007. For the comparable period of 2006, we incurred $1,000 of expense.

Other Income and Expenses. Other expense was $0.2 million, net of $0.1 million of interest income. Other income primarily consists of interest earned on our cash and cash equivalents and interest expense reflects the interest incurred on the debt we assumed from Acuity as part of the Merger as well as $4.0 million drawn down from our line of credit.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2007 AND PERIOD FROM INCEPTION (JUNE 23, 2006) THROUGH SEPTEMBER 30, 2006

The results of operations for the first nine months of 2007 include Froptix' operating results for the full nine month period, and Acuity's operating results subsequent to March 27, 2007. As a result of the reverse merger, historical comparative results are those of Froptix only. Froptix was incorporated on June 23, 2006 and as a result, did not have significant operations for most of the first eight days and three months ended September 30, 2006.

Selling, General and Administrative Expense. Selling, general and administrative expense for the first nine months of 2007 was $8.2 million. General and administrative expense primarily included personnel costs, including stock-based compensation and professional fees. During 2007, we anticipate general and administrative expense to increase to reflect the costs of being an operating public company. We incurred costs related to building a commercial infrastructure during the nine months ended September 30, 2007 in preparation of the acquisition of OTI and expect these activities to continue to increase throughout 2007.

Research and Development Expense. Research and development expense for the first nine months of 2007 was $7.0 million. Research and development expense primarily related to personnel costs, including stock-based compensation as well as costs related to the initiation of the Phase III clinical trial for bevasiranib. During the third quarter of 2007, a reversal of equity based compensation expense of $8.1 million was recorded as a result of the termination of a consulting agreement prior to the vesting of any of the equity based awards issued under the consulting agreement. Originally, this expense was accrued $0.3 million during 2006 and $7.8 million during the first

six months of 2007.

Research and development expense during 2007 will primarily relate to our bevasiranib program including costs to prepare for our Phase III clinical study for bevasiranib. We initiated enrollment of our Phase III clinical trial for bevasiranib in July 2007. We currently expect the total cost of this trial to be approximately $25 million, although this estimate could vary significantly as the Phase III clinical trial progresses.

Write-off of Acquired In-Process Research and Development. On March 27, 2007, we acquired Acuity 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 the transaction and two days prior to the transaction. We recorded the assets and liabilities at fair value, and as a result, we recorded acquired in-process research and development expense and recorded a charge of $243.8 million.

Other Income and Expenses. Other expense was $0.4 million, net of $0.2 million of interest income. Other income primarily consists of interest earned on our cash and cash equivalents and interest expense reflects the interest incurred during the period from March 27, 2007 September 30, 2007 on the debt we assumed from Acuity as part of the merger as well as $4.0 million drawn down from our line of credit.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2007, we had cash and cash equivalents of approximately $4.7 million. Cash used in operations primarily reflects our net loss, offset by our non-cash operating expenses including the write-off of in-process research and development acquired in the Merger and stock based compensation expense. Since our inception, we have not generated revenue and our primary source of cash has been from the private placement of stock and through credit facilities available to us.

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 of the equity in OTI on a fully diluted basis. The $5.0 million will be used by OTI for working capital. In addition to the one-third interest, we also received an exclusive right to purchase the remaining outstanding shares of OTI for $10 million, payable by issuance of our common stock subject to a collar limiting the number of shares to be issued to be between 2.8 and 3.1 million shares. We have elected to exercise the option to acquire the remaining shares of OTI and are negotiating definitive transaction documents relating to the acquisition.

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 2007. Principal on the term loan matures as follows: $1.7 million during 2007, or which, $0.6 million has been through September 30, 2007 and $2.3 million during 2008. The term loan is collateralized by all personal property of the Acuity, except intellectual property, and contains certain negative covenants that limit the payment of cash dividends, redemption of equity securities, change in ownership, and the creation or extinguishment of debt. In connection with the issuance of the term note, Acuity issued warrants to purchase 200,000 shares of Series B at $2.00 per share which converted to 1,037,900 shares and 235,932 shares, respectively; of our common stock upon consummation of the Mergers in addition to warrants to purchase 25,000 shares of common stock at $0.01 per share, which converted to 129,736 warrants to purchase our common stock upon consummation of the Mergers.

In connection with the consummation of the Mergers, we assumed the rights and obligations of Acuity under the line of credit Acuity had with the Frost Group. We also amended and restated the Frost Group line of credit to provide additional available borrowing capacity. Under this amended and restated line of credit, we gained access to $8.0 million in available borrowings and we assumed Acuity’s existing obligation to repay $4.0 million outstanding under the 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, capitalized quarterly on outstanding borrowings under the line of credit at a 10% annual rate, which is due June 11, 2009. 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 OPKO ($11.0 million) and debt commitment fee ($0.1 million).

We expect to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that general and administrative expenses will also increase as we expand our finance and administrative staff, add infrastructure, and incur additional costs related to being a public company, including the costs of directors' and officers' insurance, investor relations programs, and increased professional fees.

The cash and cash equivalents on hand and our available credit line at September 30, 2007 will not be sufficient to meet our anticipated cash requirements for operations and debt service for at least the next 12 months and we will require additional funding during the first half of 2008. We intend to finance our future operations with a combination of private placements, payments from potential strategic research and development, licensing and/or marketing arrangements, public offerings, debt financing and revenues from future product sales, if any. There can be no assurance that additional capital will be available to us on acceptable terms, or at all.

CRITICAL ACCOUNTING POLICIES

We believe the following critical accounting policies affect management's more significant judgments and estimates used in the preparation of our financial statements.

Impairment of Long-Lived Assets. In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*, 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, management believes that no revision of the remaining useful lives or write-down of long-lived assets is required.

Stock-Based Compensation. As of June 23, 2006 (the date of inception) we, adopted SFAS No. 123(R), *Share-Based Payments* SFAS No. 123(R) replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB No. 25. SFAS No. 123(R) requires that all stock-based compensation be recognized as an expense in the financial statements and that such cost be measured at the fair value of the award. We adopted the modified prospective transition method provided for under SFAS No. 123(R). Under this transition method, compensation cost recognized in 2006 associated with stock options includes (i) amortization related to all stock option awards granted/modified on or subsequent to January 1, 2006, based on the estimated grant date fair value using the Black-Scholes option-pricing model, and (ii) amortization of the intrinsic value recorded as deferred compensation for options granted prior to January 1, 2006 being accounted for under APB Opinion No. 25. Option awards granted prior to adoption of SFAS No. 123(R) continue to follow the provisions of APB Opinion No. 25 and FIN 44 until modified and or settled.

Prior to the adoption of SFAS No. 123(R), we presented all tax benefits resulting from the exercise of stock options as operating cash flows in the statements of cash flows. SFAS No. 123(R) requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as financing cash flows. We have sufficient net operating loss carryforwards to generally eliminate cash payments for income taxes. Therefore, no cash has been retained as a result of excess tax benefits relating to share based payments made to directors and employees.

NEW ACCOUNTING PRONOUNCEMENTS

In July 2006, the Financial Accounting Standards Board, or FASB, issued Interpretation Number, or FIN, No. 48, *Accounting for Uncertainty in Income Taxes*, or FIN 48. FIN 48 applies to all tax positions within the scope of SFAS No. 109, applies a "more likely than not" threshold for tax benefit recognition, identifies a defined methodology for

measuring benefits and increases the disclosure requirements for companies. FIN 48 is mandatory for years beginning after December 15, 2006; accordingly, we have adopted FIN 48 effective January 1, 2007. Refer to Note 6.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* , or SFAS No. 157. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles and expands disclosures about fair value measurements. This Statement applies to other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. SFAS No. 157 is effective for fiscal years beginning after December 15, 2007. We plan to adopt SFAS No. 157 beginning in the first quarter of our 2008 fiscal year. We are currently evaluating the impact the adoption of SFAS No. 157 may have on our financial position and results of operations.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS No. 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 No. 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the impact the adoption of SFAS No. 159 may have on our financial position and the results of operations.

In June 2007, the Emerging Issues Task Force, or EITF, issued EITF 07-3 *Accounting for Advance Payments for Goods or Services to be Received for Use in Future Research and Development Activities*. This EITF establishes that prepayments made related to research and development goods and services should be capitalized and recognized as expense when the goods are received or the services have been preformed. The prepaid assets must be assessed for recoverability to ensure the prepaid goods or services will continue to be used. EITF 07-3 is effective for new contracts entered into in fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We are currently evaluating the impact the adoption of EITF 07-3 may have on our financial position and the results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

In the normal course of doing business we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates. We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or “other than trading” instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk.

Our exposure to market risk relates to our cash and investments and to our borrowings. We maintain an investment portfolio of money market funds and qualified purchaser funds. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than one month.

Item 4. Controls and Procedures

An evaluation was carried out by management under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the Company's "Disclosure Controls and Procedures" as of September 30, 2007. They have concluded as of September 30, 2007, that our Disclosure Controls and Procedures were effective at providing reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 are recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure Controls and Procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in such reports is accumulated and communicated to the Company's management, as appropriate to allow timely decisions regarding required disclosure.

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.

We are a development-stage specialty healthcare company with a limited operating history. We are not profitable and have incurred losses since our inception. We do not anticipate that we will generate revenue from the sale of pharmaceutical products for the foreseeable future. We have not yet submitted any pharmaceutical products for approval or clearance by regulatory authorities and we do not currently have rights to any pharmaceutical product candidates that have been approved for marketing. We continue to incur research and development and general and administrative expenses related to our operations and, to date, we have devoted most of our financial resources to research and development, including our pre-clinical development activities and clinical trials. We expect to continue to incur losses from our pharmaceutical operations for the foreseeable future, and we expect these losses to increase as we continue our research activities and conduct development of, and seek regulatory approvals and clearances for, our product candidates, and prepare for and begin to commercialize any approved or cleared products. If our product candidates fail in clinical trials or do not gain regulatory approval or clearance, or if our product candidates do not achieve market acceptance, we may never become profitable. In addition, if we are required by the U.S. Food and Drug Administration, or the FDA, to perform studies in addition to those we currently anticipate, our expenses will increase beyond expectations and the timing of any potential product approval may be delayed. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Our technologies are in an early stage of development and are unproven.

We are engaged in the research and development of pharmaceutical products, drug delivery technologies and diagnostic systems and instruments for the treatment and prevention of ophthalmic diseases. The effectiveness of our technologies is not well-known in, or accepted generally by, the clinical medical community. There can be no assurance that we will be able to successfully employ our technologies as therapeutic, diagnostic or preventative solutions for any ophthalmic disease. Our failure to establish the efficacy or safety of our technologies would have a material adverse effect on our business.

In addition, we have a limited operating history. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our pharmaceutical product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our product research and development activities may not result in commercially viable products.

Most of our product candidates are in the very early stages of development and are prone to the risks of failure inherent in drug and medical device product development. We will likely be required to complete and undertake significant additional clinical trials to demonstrate to the FDA that our product candidates are safe and effective to the satisfaction of the FDA and other non-United States regulatory authorities or for their intended uses, or are substantially equivalent in terms of safety and effectiveness to an existing, lawfully marketed non-premarket approved device. Clinical trials are expensive and uncertain processes that often take years to complete. Failure can occur at any stage of the process, and successful early positive results do not ensure that the entire clinical trial or later clinical trials will be successful. Product candidates in clinical-stage trials may fail to show desired efficacy and safety traits despite early promising results.

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.

Bevasiranib has been studied in a Phase II clinical drug trial for the treatment of Wet AMD, and we are presently studying bevasiranib in Phase III clinical trials. Our Phase III clinical trials may not be successful, and bevasiranib may never receive regulatory approval or be successfully commercialized. Our clinical development program for bevasiranib may not receive regulatory approval if we fail to demonstrate that it is safe and effective in clinical trials and, consequently, fail to obtain necessary approvals from the FDA, or similar non-United States regulatory agencies, or if we have inadequate financial or other resources to advance bevasiranib through the clinical trial process. Even if bevasiranib receives regulatory approval, its approved labeling may be insufficient to permit adequate marketing. We may not be successful in marketing it for a number of other reasons, including the introduction by our competitors of more clinically-effective or cost-effective alternatives or failure in our sales and marketing efforts. Any failure to obtain approval of bevasiranib and successfully commercialize it would have a material and adverse impact on our business.

The results of pre-clinical trials and 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.

Positive results from pre-clinical studies and early clinical trial experience should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates either (i) are safe and effective for use in a diverse population of their intended uses or (ii) with respect to Class I or Class II devices only, are substantially equivalent in terms of safety and effectiveness to devices that are already marketed under section 510(k) of the Food, Drug and Cosmetic Act. Success in early clinical trials does not mean that future clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other non-United States regulatory authorities despite having progressed through initial clinical trials.

Further, our drug candidates may not be approved or cleared even if they achieve their primary endpoints in Phase III clinical trials or registration trials nor may our device candidates be approved or cleared, as the case may be, even though clinical or other data are, in our view, adequate to support a device approval or clearance. The FDA or other non-United States regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval or clearance of a product candidate even after reviewing and providing comment on a protocol for a pivotal clinical trial that has the potential to result in FDA approval. In addition, any of these regulatory authorities may also approve or clear a product candidate for fewer or more limited indications or uses than we request or may grant approval or clearance contingent on the performance of costly post-marketing clinical trials. In addition, the FDA or other non-United States regulatory authorities may not approve the labeling claims necessary or desirable for the

successful commercialization of our product candidates.

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 of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.

We are advancing and intend to continue to advance multiple product candidates through clinical and pre-clinical development. We will need to raise substantial additional capital to engage in and continue our clinical and pre-clinical development and commercialization activities. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through public or private equity offerings, debt financings or strategic collaborations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

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 life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical, biotechnology and medical device companies that are researching and marketing products designed to address AMD and other ophthalmic diseases and conditions. We are currently developing therapeutics, diagnostic and preventative products that will compete with other drugs, therapies and medical devices that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs, therapies and medical devices. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals or clearances for drugs or medical devices. These companies also have significantly greater research and marketing capabilities than we do. Some of the pharmaceutical companies we expect to compete with include Genentech, Allergan, Alcon Laboratories, Regeneron, QLT, Pfizer, Alnylam and Bausch & Lomb. In addition, many universities and private and public research institutions may become active in ophthalmic disease research. Compared to us, many of our potential competitors have substantially greater capital resources, development resources, including personnel and technology, clinical trial experience, regulatory experience, expertise in prosecution of intellectual property rights, manufacturing and distribution experience and sales and marketing experience. The development of other promising drugs for the treatment of Dry AMD, which in certain patients is the precursor to Wet AMD, could materially adversely affect the prospects for bevasiranib and other treatments for Wet AMD.

28

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 technologies or product candidates obsolete or less competitive.

Our product development activities could be delayed or stopped.

We do not know whether our planned clinical trials will be completed on schedule, or at all, and we cannot guarantee that our planned clinical trials will begin on time or at all. The commencement of our planned clinical trials could be substantially delayed or prevented by several factors, including:

- a limited number of, and competition for, suitable patients with the particular types of ophthalmic disease required for enrollment in our clinical trials or that otherwise meet the protocol’s inclusion criteria and do not meet any of the exclusion criteria;
- a limited number of, and competition for, suitable sites to conduct our clinical trials;
- delay or failure to obtain FDA approval or agreement to commence a clinical trial;
- delay or failure to obtain sufficient supplies of the product candidate for our clinical trials;

- requirements to provide the drugs or medical devices required in our clinical trial protocols or clinical trials at no cost or cost, which may require significant expenditures that we are unable or unwilling to make;

- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and

- delay or failure to obtain institutional review board, or IRB, approval to conduct or renew a clinical trial at a prospective or accruing site.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment;

- failure of patients to complete the clinical trial;
- unforeseen safety issues;
- lack of efficacy evidenced during clinical trials;
- termination of our clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols; and
- inability to monitor patients adequately during or after treatment.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB for any given site, or us. Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Any failure or significant delay in completing clinical trials for our product candidates could materially harm our financial results and the commercial prospects for our product candidates.

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.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products or medical devices are subject to extensive regulation by the FDA and other non-United States regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a new drug application, or NDA, a clearance letter under the premarket notification process, or 510(k) process, or an approval of a pre-market approval, or PMA, from the FDA. We have not submitted an NDA or PMA application or premarket notification, nor have we received marketing approval or clearance for any of our pharmaceutical product candidates. Obtaining approval of an NDA or PMA can be a lengthy, expensive and uncertain process. With respect to medical devices, while the FDA normally reviews and clears a premarket notification in three months, there is no guarantee that our products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance that even if a device is reviewed under the 510(k) process that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non-PMA device. If the FDA fails to make this finding, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product. In addition, failure to comply with FDA, non-United States regulatory authorities or other applicable United States and non-United States regulatory requirements may, either before or after product approval or clearance, if any, subject our company to administrative or judicially imposed sanctions, including, but not limited to the following:

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations (Form 483), warning letters or non-warning letters incorporating inspectional observations;
- civil and criminal penalties;
- injunctions;

- suspension or withdrawal of regulatory approvals or clearances;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve or clear pending NDAs or supplements to approved NDAs, applications or pre-market notifications.

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:

- a drug 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 of the drug supplemented by clinical trial results that address the change (e.g., route of administration). The Company is not presently involved in clinical trials for a section 505(b)(2) drug or the submission of an NDA for such a drug, but could be in the future. If the Company were to submit an NDA under that section, the Company could be sued for patent infringement by the pharmaceutical company that owns the patent on the existing approved NDA drug. Such a suit would automatically preclude the FDA from processing our NDA for 30 months and possibly longer. Defending such a suit would be costly. If we were to lose the litigation, we could be precluded from marketing the product until the NDA holder's patent expires. Such an adverse result would interfere with out strategic plans and would therefore have adverse financial implications for the company.

Our product candidates may have undesirable side effects and cause our approved drugs to be taken off the market.

If a product candidate receives marketing approval and we or others later identify undesirable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;

- 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 our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our future product candidates and we may not achieve or sustain profitability.

Even if we receive regulatory approval or clearance to market our product candidates, the market may not be receptive to our products.

Even if our product candidates obtain regulatory approval or clearance, resulting products may not gain market acceptance among physicians, patients, health care payors and/or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including:

- timing of market introduction of competitive products;

· the safety and efficacy of our product compared to other products;

· prevalence and severity of any side effects;

- 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 (not 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 attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Our success depends on our continued ability to attract, retain and motivate highly qualified management and pre-clinical and clinical personnel. The loss of the services of any of our senior management, including Dr. Phillip Frost, our Chairman of the Board and Chief Executive Officer, could delay or prevent the development and commercialization of our product candidates. We do not maintain “key man” insurance policies on the lives of any of our employees. We will need to hire additional personnel as we continue to expand our research and development activities and build a sales and marketing function.

We have scientific and clinical advisors who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical, medical device and other similar businesses. If we are unable to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy. In particular, if we lose any members of our senior management team, we may not be able to find suitable replacements in a timely fashion or at all and our business may be harmed as a result.

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.

As we advance our product candidates through clinical trials, research and development we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with such third parties, as well as additional collaborators and suppliers. Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to: manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems; and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

Furthermore, we may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired business or product could be expensive and time-consuming. We may not be able to integrate any acquired business or product successfully or operate any acquired business profitably, including our OPKO Ophthalmologics and Froptix subsidiaries. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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 intend to continue to rely on acquisitions and in-licensing as the source of our products and product candidates for development and commercialization. The success of this strategy depends upon our ability to identify, select and acquire pharmaceutical products, drug delivery technologies and medical device product candidates. Proposing, negotiating and implementing an economically viable product acquisition or license is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical, biotechnology and medical device companies and academic research institutions. Our competitors may have stronger relationships with third parties with whom we are interested in collaborating and/or may have more established histories of developing and commercializing products. As a result, our competitors may have a competitive advantage in entering into partnering arrangements with such third parties. In addition, even if we find promising product candidates, and generate interest in a partnering or strategic arrangement to acquire such product candidates, we may not be able to acquire rights to additional product candidates or approved products on terms that we find acceptable, or at all.

34

We expect that any product candidate to which we acquire rights will require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and other non-United States regulatory authorities. All product candidates are subject to the risks of failure inherent in pharmaceutical or medical device product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. Even if the product candidates are approved or cleared, we cannot be sure that they would be capable of economically feasible production or commercial success.

We have no experience or capability manufacturing large clinical-scale or commercial-scale products, and have no manufacturing facility; we therefore rely on third parties to manufacture and supply our product candidates.

We believe we currently have, or can access, sufficient supplies of bevasiranib to conduct and complete our planned Phase III clinical trials. If our manufacturing partners are unable to produce bevasiranib or our other products in the amounts that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the quantities we require. We expect to continue to depend on third-party contract manufacturers for the foreseeable future.

Our product candidates require precise, high quality manufacturing. Any of our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and other non-United States regulatory authorities to ensure strict compliance with QSR regulations for devices or cGMPs for drugs, and other applicable government regulations and corresponding standards relating to matters such as testing, quality control and documentation procedures. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with QSR or cGMPs, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business.

Any performance failure on the part of our contract manufacturers could delay clinical development or regulatory approval or clearance of our product candidates or commercialization of our future product candidates, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on a third party for manufacturing may adversely affect our future profit margins. Our ability to replace an existing manufacturer may be difficult because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer before it can begin manufacturing our product candidates. Such approval would result in additional non-clinical testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

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 and contract research organizations that we engage to conduct our clinical trials may not be diligent, careful or timely.

We will depend on independent clinical investigators to conduct our clinical trials. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to products that we develop. If independent investigators fail to devote sufficient resources to the development of product candidates or clinical trials, or if their performance is substandard, it will delay the approval or clearance and commercialization of any products that we develop. Further, the FDA requires that we comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research organizations fail to comply with good clinical practice, the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed. Failure of clinical investigators or contract research organizations to meet their obligations to us or comply with federal regulations and good clinical practice procedures could adversely affect the clinical development of our product candidates and harm our business.

The success of our business may be dependent on the actions of our collaborative partners.

We expect to enter into collaborative arrangements with established multinational pharmaceutical and medical device companies which will finance or otherwise assist in the development, manufacture and marketing of products incorporating our technology. We anticipate deriving some revenues from research and development fees, license fees, milestone payments and royalties from collaborative partners. Our prospects, therefore, may depend to some extent upon our ability to attract and retain collaborative partners and to develop technologies and products that meet the requirements of prospective collaborative partners. In addition, our collaborative partners may have the right to abandon research projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed-upon research terms. There can be no assurance that we will be successful in establishing

collaborative arrangements on acceptable terms or at all, that collaborative partners will not terminate funding before completion of projects, that our collaborative arrangements will result in successful product commercialization or that we will derive any revenues from such arrangements. To the extent that we are unable to develop and maintain collaborative arrangements, we would need substantial additional capital to undertake research, development and commercialization activities on our own.

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 Intradigm.

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 other 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 third-party intellectual property in the future.

Our success will depend in part on our ability or the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property and, in particular, those patents to which we have secured exclusive rights in our field. We or our licensors may not successfully prosecute the patent applications which are licensed to us. Even if patents issue in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we have licensed, other

companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief from an infringement and may be unable to enjoin infringement, which could materially diminish the value of the patent.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products or impair our competitive position. In addition, to the extent that a third party develops new technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available or may not be available on commercially reasonable terms, if at all. If licenses are not available to us on acceptable terms, we will 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 circumvent the third-party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations.

Additionally, RNAi is a relatively new scientific field that has generated many different patent applications from organizations and individuals seeking to obtain important patents in the field. These applications claim many different methods, compositions and processes relating to the discovery, development and commercialization of RNAi therapeutics. Because the field is so new, very few of these patent applications have been fully processed by government patent offices around the world, and there is a great deal of uncertainty about which patents will issue, when, to whom, and with what claims. It is likely that there will be significant litigation and other proceedings, such as interference and opposition proceedings in various patent offices, relating to patent rights in the RNAi field. Others may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes among third parties could impact our intellectual property rights.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts.

Third parties may sue us for infringing their patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of proprietary rights of others. In addition, a third-party may claim that we have improperly obtained or used its confidential or proprietary information. Furthermore, in connection with our third-party license agreements, we generally have agreed to indemnify the licensor for costs incurred in connection with litigation relating to intellectual property rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert our management’s efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have

willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Medicare legislation and future legislative or regulatory reform of the health care system may affect our ability to sell our products profitably.

In the United States, there have been a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products profitably. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, extended Medicare, effective January 1, 2006, to cover most outpatient prescription drugs that are not administered by physicians and modified, effective January 1, 2004, the methodology used by Medicare to reimburse for those drugs administered by physicians. Our business could be harmed by the MMA, by the possible effect of this legislation on amounts that private payors will pay and by other healthcare reforms that may be enacted or adopted in the future. To the extent that our products are deemed to be durable medical equipment, they may be subject to distribution under the new Competitive Acquisition regulations, also part of MMA, and this could adversely affect the amount that patients or medical providers can seek from payors. Non-durable medical equipment devices used in surgical procedures are normally paid directly by the hospital or health care provider and not reimbursed separately by third-party payors. As a result, these types of devices are subject to intense price competition that can place a small manufacturer at a competitive disadvantage.

We are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business. Any cost containment measures or other health care system reforms that are adopted could have a material adverse effect on our ability to commercialize our existing and future product candidates successfully.

Failure to obtain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.

We intend to market certain of our existing and future product candidates in non-United States markets. In order to market our existing and future product candidates in the European Union and many other non-United States jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with non-United States regulatory authorities, the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval or clearance. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non-United States regulatory authority does not ensure approval by other regulatory authorities in other countries or by the FDA. The non-United States regulatory approval process may include all of the risks associated with obtaining FDA approval or clearance. We may not obtain non-United States regulatory approvals on a timely basis, if at all. We may not be able to file for non-United States regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market.

Acquisitions may result in disruptions to our business or distractions of our management and may not proceed as planned.

We intend to continue to expand our business through the acquisition of companies, technologies, products and services. Acquisitions involve a number of special problems and risks, including, but not limited to:

· difficulty integrating acquired technologies, products, services, operations and personnel with the existing businesses;

- 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 revenues, earnings or business synergies that we anticipated, and acquired products, services or technologies might not perform as we expected. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We may not be able to successfully address these problems and we cannot assure you that the acquisitions will be successfully identified and completed or that, if acquisitions are completed, the acquired businesses, products, services or technologies will generate sufficient revenue to offset the associated costs or other harmful effects on our business.

Any of these risks can be greater if an acquisition is large relative to our size. Failure to manage effectively our growth through acquisitions could adversely affect our growth prospects, business, results of operations and financial condition.

Non-United States governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market certain of our existing and future product candidates in both the United States and in non-United States jurisdictions. If we obtain approval in one or more non-United States jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug or medical device candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our existing and future product candidates to other available products. If reimbursement of our future product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Our business may become subject to economic, political, regulatory and other risks associated with international operations.

Our business is subject to risks associated with conducting business internationally, in part due to a number of our suppliers being located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- difficulties in compliance with non-United States laws and regulations;

- changes in non-United States regulations and customs;
- changes in non-United States currency exchange rates and currency controls;
- changes in a specific country’s or region’s political or economic environment;

· trade protection measures, import or export licensing requirements or other restrictive actions by United States or non-United States governments;

· negative consequences from changes in tax laws; and

· difficulties associated with staffing and managing foreign operations, including differing labor relations.

The market price of our common stock may fluctuate significantly.

The market price of our common stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

· the announcement of new products or product enhancements by us or our competitors;

· developments concerning intellectual property rights and regulatory approvals;

· variations in our and our competitors' results of operations;

· changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts;

· developments in the biotechnology, pharmaceutical and medical device industry;

· the results of product liability or intellectual property lawsuits;

· future issuances of common stock or other securities;

· the addition or departure of key personnel;

· announcements by us or our competitors of acquisitions, investments or strategic alliances; and

· general market conditions and other factors, including factors unrelated to our operating performance.

Further, the stock market in general, and the market for biotechnology, pharmaceutical and medical device companies in particular, has recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock.

Some or all of the "restricted" shares of our common stock issued to former stockholders of Froptix and Acuity in connection with the acquisition or held by other of our stockholders may be offered from time to time in the open market pursuant to an effective registration statement or Rule 144, and these sales may have a depressive effect on the market for our common stock.

Trading restrictions imposed on us by applicable regulations and by lockup agreements we have entered into with our principal stockholders may reduce our trading, making it difficult for our stockholders to sell their shares.

Approximately 68% of the outstanding shares of our common stock (including outstanding shares of our preferred stock on an as converted basis) are subject to lockup agreements which limit sales for a two-year period from March 27, 2007. These factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our common stock. In addition, without a large float,

our common stock is less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. We cannot predict the prices at which our common stock will trade in the future.

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.
Exhibit 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 for the quarterly period ended September 30, 2007.
Exhibit 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 for the quarterly period ended September 30, 2007.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 14, 2007

OPKO Health, Inc.

/s/ Adam Logal

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