

Opko Health, Inc.  
Form 10-Q  
November 09, 2011  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, DC 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2011.

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from            to            .

Commission file number 001-33528

**OPKO Health, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**75-2402409**  
(I.R.S. Employer  
Identification No.)

**4400 Biscayne Blvd.**  
**Miami, FL 33137**

(Address of Principal Executive Offices) (Zip Code)

**(305) 575-4100**

(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  NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

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

Large Accelerated filer  Accelerated filer

Non-Accelerated filer  (Do not check if a smaller reporting company) Smaller Reporting Company

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

As of November 1, 2011, the registrant had 290,272,310 shares of common stock outstanding.

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**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q contains forward-looking statements, as that term is defined under the Private Securities Litigation Reform Act of 1995, or PSLRA, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in Item 1A-Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2010, and described from time to time in our reports filed with the Securities and Exchange Commission. Except as required by law, we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Risks and uncertainties, the occurrence of which could adversely affect our business, include the following:

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

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

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

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-U.S. regulatory authorities.

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

Our business is substantially dependent on our ability to develop, launch and generate revenue from our molecular diagnostic program.

We expect to finance future cash needs primarily through public or private offerings, debt financings or strategic collaborations, which may dilute your stockholdings in the Company.

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.

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Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes.

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

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

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

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

We have no experience manufacturing our pharmaceutical product candidates other than at our Mexican facility and we therefore rely on third parties to manufacture and supply our pharmaceutical product candidates, and would need to meet various standards necessary to satisfy FDA regulations if and when we commence manufacturing.

We currently have no pharmaceutical or diagnostic marketing, sales or distribution capabilities other than in Chile and Mexico for sales in those countries. If we are unable to develop our sales and marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our pharmaceutical product candidates.

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

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

Our license agreement with TESARO, Inc. is important to our business. If TESARO does not successfully develop and commercialize rolapitant, our business could be adversely affected.

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

We do not have an exclusive arrangement in place with Dr. Tom Kodadek with respect to technology or intellectual property that may be material to our business.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We rely heavily on licenses from third parties.

We license patent rights to certain of our technology from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

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

Adverse results in material litigation matters or governmental inquiries could have a material adverse effect upon our business and financial condition.

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

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

We may not have the funding available to pursue acquisitions.

Acquisitions may disrupt our business, distract our management and may not proceed as planned; and we may encounter difficulties in integrating acquired businesses.

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

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

The market price of our common stock may fluctuate significantly.

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

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

If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as they apply to us, or our internal controls over financial reporting are not effective, the reliability of our financial statements may be questioned and our common stock price may suffer.

We may be unable to maintain our listing on the NYSE, which could cause our stock price to fall and decrease the liquidity of our common stock.

Future issuances of common stock and hedging activities may depress the trading price of our common stock.

Provisions in our charter documents and Delaware law could discourage an acquisition of us by a third party, even if the acquisition would be favorable to you.

We do not intend to pay cash dividends on our common stock in the foreseeable future.



**Table of Contents****PART I. FINANCIAL INFORMATION**

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to the Company, OPKO, we, our, ours, and us to OPKO Health, Inc., a Delaware corporation, including our wholly-owned subsidiaries.

**Item 1. Financial Statements****OPKO Health, Inc. and Subsidiaries****CONDENSED CONSOLIDATED BALANCE SHEETS**

(unaudited)

(in thousands except share and per share data)

	September 30, 2011	December 31, 2010
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 47,235	\$ 18,016
Marketable securities	40,182	
Accounts receivable, net	12,688	11,856
Inventory, net	10,516	16,423
Prepaid expenses and other current assets	1,729	2,679
Current assets of discontinued operations	5,279	5,098
<b>Total current assets</b>	<b>117,629</b>	<b>54,072</b>
Property and equipment, net	3,271	2,589
Intangible assets, net	14,252	6,784
Goodwill	6,234	5,856
Investments	5,862	5,114
Other assets	824	111
Assets of discontinued operations	2,929	3,320
<b>Total assets</b>	<b>\$ 151,001</b>	<b>\$ 77,846</b>
<b>LIABILITIES, SERIES D PREFERRED STOCK, AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 2,556	\$ 6,479
Accrued expenses	3,678	3,370
Current portion of lines of credit	12,547	14,690
Current liabilities of discontinued operations	1,460	3,060
<b>Total current liabilities</b>	<b>20,241</b>	<b>27,599</b>
Long-term liabilities	2,154	1,067
<b>Total liabilities</b>	<b>22,395</b>	<b>28,666</b>
Commitments and contingencies		
Series D Preferred Stock - \$0.01 par value, 2,000,000 shares authorized; 1,209,677 shares issued and outstanding (liquidation value of \$34,813 and \$33,013) at September 30, 2011 and December 31, 2010, respectively	26,128	26,128

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### Shareholders' equity

Series A Preferred stock - \$0.01 par value, 4,000,000 shares authorized; 0 and 897,439 shares issued and outstanding (liquidation value of \$0 and \$2,468) at September 30, 2011 and December 31, 2010, 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; 288,141,824 and 255,412,706 shares issued at September 30, 2011 and December 31, 2010, respectively	2,881	2,554
Treasury stock - 2,443,894 and 45,154 shares at September 30, 2011 and December 31, 2010, respectively	(7,893)	(61)
Additional paid-in capital	485,181	376,008
Accumulated other comprehensive income	434	2,921
Accumulated deficit	(378,125)	(358,379)
Total shareholders' equity	102,478	23,052
Total liabilities, Series D preferred stock, and Shareholders' equity	\$ 151,001	\$ 77,846

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

**Table of Contents****OPKO Health, Inc. and Subsidiaries****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(unaudited)

(in thousands, except share and per share amounts)

	For the three months ended September 30,		For the nine months ended September 30,	
	2011	2010	2011	2010
<b>Revenue</b>				
Product sales	\$ 6,760	\$ 5,678	\$ 22,113	\$ 16,262
Other revenue	47		72	
<b>Total Revenue</b>	<b>6,807</b>	<b>5,678</b>	<b>22,185</b>	<b>16,262</b>
Cost of goods sold, excluding amortization of intangible assets	4,017	3,348	13,085	10,145
<b>Gross margin, excluding amortization of intangible assets</b>	<b>2,790</b>	<b>2,330</b>	<b>9,100</b>	<b>6,117</b>
<b>Operating expenses</b>				
Selling, general and administrative	4,348	4,440	14,102	12,802
Research and development	3,301	1,543	7,097	3,634
Other operating expenses, principally amortization of intangible assets	945	568	2,615	1,558
<b>Total operating expenses</b>	<b>8,594</b>	<b>6,551</b>	<b>23,814</b>	<b>17,994</b>
Operating loss from continuing operations	(5,804)	(4,221)	(14,714)	(11,877)
Other expense, net	(671)	(320)	(757)	(1,047)
<b>Loss from continuing operations before income taxes and investment loss</b>	<b>(6,475)</b>	<b>(4,541)</b>	<b>(15,471)</b>	<b>(12,924)</b>
Income tax (benefit) provision	(27)	83	199	184
<b>Loss from continuing operations before investment losses</b>	<b>(6,448)</b>	<b>(4,624)</b>	<b>(15,670)</b>	<b>(13,108)</b>
Loss from investments in investees	(301)	(208)	(1,175)	(683)
<b>Loss from continuing operations</b>	<b>(6,749)</b>	<b>(4,832)</b>	<b>(16,845)</b>	<b>(13,791)</b>
Loss from discontinued operations, net of tax	(1,487)	(2,522)	(2,841)	(4,462)
<b>Net loss</b>	<b>(8,236)</b>	<b>(7,354)</b>	<b>(19,686)</b>	<b>(18,253)</b>
Preferred stock dividend	(600)	(656)	(1,860)	(1,979)
<b>Net loss attributable to common Shareholders</b>	<b>\$ (8,836)</b>	<b>\$ (8,010)</b>	<b>\$ (21,546)</b>	<b>\$ (20,232)</b>
<b>Loss per share, basic and diluted</b>				
Loss per share from continuing operations	\$ (0.02)	\$ (0.02)	\$ (0.06)	\$ (0.05)
<b>Loss per share</b>	<b>\$ (0.03)</b>	<b>\$ (0.03)</b>	<b>\$ (0.08)</b>	<b>\$ (0.08)</b>

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Weighted average number of common shares outstanding, basic and diluted	285,582,259	255,252,433	277,359,789	254,854,652
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*The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.*

**Table of Contents****OPKO Health, Inc. and Subsidiaries****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(unaudited)

(in thousands)

	For the nine months ended September 30,	
	2011	2010
Cash flows from operating activities		
Loss from continuing operations	\$ (16,845)	\$ (13,791)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,858	1,712
Accretion of debt discount related to notes payable	2	248
Equity-based compensation employees and non-employees	5,350	3,808
Loss from investments in investees	1,175	683
Provision for (recovery of) bad debt	260	(8)
Provision for inventory reserves	534	25
Changes in:		
Accounts receivable	(2,523)	(2,847)
Inventory	4,080	(3,555)
Prepaid expenses and other current assets	224	(263)
Other assets	53	18
Accounts payable	(3,652)	1,372
Accrued expenses	852	(3,731)
Cash used in operating activities from continuing operations	(7,632)	(16,329)
Cash used in operating activities from discontinuing operations	(4,280)	(927)
Net cash used in operating activities	(11,912)	(17,256)
Cash flows from investing activities		
Acquisition of businesses, net of cash	(10,538)	(1,323)
Investment in Neovasc	(2,013)	
Purchase of marketable securities	(100,161)	(14,997)
Maturities of short-term marketable securities	59,982	14,997
Capital expenditures	(1,249)	(601)
Cash used in investing activities from continuing operations	(53,979)	(1,924)
Cash used in investing activities from discontinued operations		(29)
Net cash used in investing activities	(53,979)	(1,953)
Cash flows from financing activities:		
Issuance of common stock, including related parties, net	104,828	
Purchase of common stock held in treasury	(7,832)	
Redemption of Series A Preferred Stock	(1,792)	
Repayment of line of credit with related party		(12,000)
Borrowings under lines of credit	10,056	5,476
Repayments under lines of credit	(10,761)	(1,874)
Proceeds from the exercise of stock options and warrants	774	26
Net cash provided by (used in) financing activities	95,273	(8,372)
Effect of exchange rate changes on cash and cash equivalents	(163)	100

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Net increase (decrease) in cash and cash equivalents	29,219	(27,481)
Cash and cash equivalents at beginning of period	18,016	42,658
Cash and cash equivalents at end of period	\$ 47,235	\$ 15,177

SUPPLEMENTAL INFORMATION

Interest paid	\$ 608	\$ 4,266
Income taxes paid, net	\$ 355	\$ (160)
Issuance of capital stock to acquire Exakta-OPKO	\$	\$ 1,999

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

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**OPKO Health, Inc. and Subsidiaries**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)**

**NOTE 1 BUSINESS AND ORGANIZATION**

We are a multi-national pharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. Our current focus is on conditions with major unmet medical needs. We are developing a range of solutions to diagnose, treat and prevent various conditions, including molecular diagnostics tests, proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets. We have already established emerging markets pharmaceutical platforms in Chile and Mexico, which are delivering revenue and which we expect to deliver cash flow and facilitate future market entry for our products currently in development. We also actively explore opportunities to acquire complementary pharmaceuticals, compounds, technologies, and businesses. We are a Delaware corporation, headquartered in Miami, Florida.

**NOTE 2 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 notes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three and nine months ended September 30, 2011, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2011 or for future periods. The interim condensed consolidated financial statements should be read in conjunction with the Consolidated Financial Statements and the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2010.

*Principles of consolidation.* The accompanying unaudited condensed consolidated financial statements include the accounts of OPKO Health, Inc. and our wholly-owned subsidiaries. All significant intercompany accounts and transactions are eliminated in consolidation.

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

*Cash and Cash Equivalents.* Cash and cash equivalents consist of short-term, interest-bearing instruments with original maturities of 90 days or less at the date of purchase. We also consider all highly liquid investments with original maturities at the date of purchase of 90 days or less as cash equivalents. These investments include money markets, bank deposits, and U.S. treasury securities.

*Marketable securities.* Investments with original maturities of greater than 90 days and remaining maturities of less than one year are classified as marketable securities. Marketable securities include U.S. treasury securities. Unrealized gains and temporary losses on investments are included in accumulated other comprehensive income (loss) as a separate component of shareholders' equity. Realized gains and losses, dividends, interest income, and declines in value judged to be other-than-temporary credit losses are included in other income (expense). Amortization of any premium or discount arising at purchase is included in interest income.

*Comprehensive loss.* Our comprehensive loss for the three and nine months ended September 30, 2011 includes net loss for the three and nine months, the unrealized loss of \$0.2 million and \$0.2 million, respectively, on our common stock options and warrants of Neovasc, Inc. (Refer to Note 5) and the cumulative translation adjustment, net, of \$2.5 million and \$2.3 million, respectively, for the translation results of our subsidiaries in Chile and Mexico. Comprehensive loss for the three and nine months ended September 30, 2010 includes net loss for the three and nine months and the cumulative translation adjustment, net, of \$2.3 million and \$0.8 million, respectively, for the translation results of our subsidiaries in Chile and Mexico.

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*Revenue recognition.* Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Certain of our instrumentation products are sold directly to end-users and require that we deliver, install and train the staff at the end-users facility. As a result, we do not recognize revenue until the product is delivered, installed and training has occurred. Refer to Note 6.

Other revenues include revenue related to upfront license payments, license fees and milestone payments received through our license, collaboration and commercialization agreements. We analyze our multiple-element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting. In addition, other revenue includes revenue related to our consulting agreement we entered into with Neovasc, Inc. (Refer to Note 5). We recognize the revenue on a straight-line basis over the contractual term of the agreement.

Non-refundable license fees for the out-license of our technology are recognized depending on the provisions of each agreement. We recognize non-refundable upfront license payments as revenue upon receipt if the license has standalone value and the fair value of our undelivered obligations, if any, can be determined. If the license is considered to have standalone value but the fair value of any of the undelivered items cannot be determined, the license payments are recognized as revenue over the period of our performance for such undelivered items or services. License fees with ongoing involvement or performance obligations are recorded as deferred revenue once received and generally are recognized ratably over the period of such performance obligation only after both the license period has commenced and we have delivered the technology. Our assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the relevant time period of research and development on a quarterly basis.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as revenue upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; there was substantive uncertainty at the date of entering into the arrangement that the milestone would be achieved; the milestone is commensurate with either the vendor's performance to achieve the milestone or the enhancement of the value of the delivered item by the vendor; the milestone relates solely to past performance; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions are not met, the milestone payments are not considered to be substantive and are, therefore, deferred and recognized as revenue over the term of the arrangement as we complete our performance obligations.

Total deferred revenue related to other revenues was \$1.0 million and \$0.2 million at September 30, 2011 and December 31, 2010, respectively.

*Derivative financial instruments.* We record derivative financial instruments on our balance sheet at their fair value and the changes in the fair value are recognized in income when they occur, the only exception being derivatives that qualify as hedges. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2011 and December 31, 2010, our forward contracts for inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in fair values in our results from operations. Refer to Note 8.



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*Product warranties.* Product warranty expense is recorded concurrently with the recording of revenue for product sales. The costs of warranties are accounted for as a component of cost of sales. We estimate warranty costs based on our estimated historical experience and adjust for any known product reliability issues.

*Allowance for doubtful accounts.* We analyze accounts receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by our estimate of the collectability of accounts receivable. Estimated allowances for sales returns are based upon our history of product returns. The amount of allowance for doubtful accounts for continuing operations at September 30, 2011 and December 31, 2010, was \$0.3 million and \$0.3 million, respectively.

*Segment reporting.* Our chief operating decision-maker ( CODM ) is comprised of our executive management with the oversight of our board of directors. Our CODM reviews our operating results and operating plans and makes resource allocation decisions on a company-wide or aggregate basis. Accordingly, we have aggregated our two operating segments, pharmaceutical operating business and pharmaceutical research and development activities into one reporting segment, pharmaceutical as we expect the businesses to have similar long-term economic characteristics. All of the results from our instrumentation business have been reclassified as discontinued operations. Refer to Note 6.

*Equity-based compensation.* We 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. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow rather than as a reduction of taxes paid in cash flow from operations. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation is subject to periodic adjustment as the underlying equity instruments vest. During the three months ended September 30, 2011 and 2010, we recorded \$1.8 million and \$1.3 million, respectively, of equity-based compensation expense for continuing operations. For the nine month periods ending September 30, 2011 and 2010, we recorded \$5.3 million, and \$3.8 million, respectively, of equity-based compensation expense for continuing operations.

*Recent accounting pronouncements.* In May 2011, the Financial Accounting Standards Board ( FASB ) issued amended accounting guidance related to fair value measurements and disclosures with the purpose of converging the fair value measurement and disclosure guidance issued by the FASB and the International Accounting Standards Board. The guidance is effective for reporting periods beginning after December 15, 2011. The guidance includes amendments that clarify the intent of the application of existing fair value measurement requirements along with amendments that change a particular principle or requirement for fair value measurements and disclosures. We concluded that the new guidance will not have a material impact on our Condensed Consolidated Statements of Operations, Condensed Consolidated Balance Sheet, or related disclosures.

In June 2011, the FASB issued amended accounting guidance related to presentation of comprehensive income. The standards update is intended to help financial statement users better understand the causes of an entity's change in financial position and results of operation. It is effective for reporting periods beginning after December 15, 2011. The amendments eliminate the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendments require that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The guidance also requires that reclassification adjustments for items that are reclassified from other comprehensive income to net income be presented on the face of the financial statement where the components of net income and other comprehensive income are presented. Upon adoption, we will continue to present components of comprehensive income in our Consolidated Statements of Operations. These statements will include reclassification adjustments as required by the new guidance for all periods presented. Since this new guidance will affect disclosure requirements only, we have concluded that it will not have a material impact on our financial position or results of operations.

In September 2011, the FASB issued ASU to amend the guidance in the ASC related to *Intangibles - Goodwill and Other*. This amendment will provide us the option of performing a qualitative assessment before calculating the fair value of the reporting unit. If it is determined that the fair value of the reporting unit is more likely than not less than the carrying amount, on the basis of qualitative factors, the two-step impairment test would be required. The amendment is effective for annual and interim goodwill impairment tests performed for our 2012 fiscal year, with earlier adoption permitted. This ASU impacts the manner in which goodwill is assessed for impairment but does not change how goodwill is calculated or assigned to reporting units, nor does it revise the requirement to test goodwill annually for impairment. It also does not change the requirement to test goodwill for impairment between annual tests if there are indicators of impairment. This ASU has no effect on our financial condition, results of operations or cash flows.

### **NOTE 3 LOSS PER SHARE**

Basic loss per share is computed by dividing our net loss by the weighted average number of shares outstanding during the period. Diluted earnings per share is computed by dividing our net loss by the weighted average number of shares outstanding and the impact of all dilutive

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potential common shares, primarily stock options. The dilutive impact of stock options and warrants are determined by applying the treasury stock method.

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A total of 26,263,152 and 20,968,353 potential common shares have been excluded from the calculation of net loss per share for the three months ended September 30, 2011 and 2010, respectively, because their inclusion would be anti-dilutive. A total of 27,375,394 and 20,067,981 potential common shares have been excluded from the calculation of net loss per share for the nine months ended September 30, 2011 and 2010, respectively, because their inclusion would be anti-dilutive. As of September 30, 2011 the holders of our Series D preferred stock could convert their preferred shares into approximately 14,037,630 shares of our Common Stock, respectively.

During the nine months ended September 30, 2011, approximately 3,389,852 common stock warrants and common stock options to purchase shares of our common stock were exercised, resulting in the issuance of 3,037,412 shares of our Common Stock. Of the 3,389,852 common stock warrants and common stock options exercised, 352,440 shares were surrendered in lieu of a cash payment via the net exercise feature of the warrant agreements.

**Table of Contents****NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS**

(in thousands)	September 30, 2011	December 31, 2010
<b>Accounts receivable, net:</b>		
Accounts receivable	\$ 13,017	\$ 12,135
Less allowance for doubtful accounts	(329)	(279)
	\$ 12,688	\$ 11,856
<b>Inventories, net:</b>		
Raw materials	\$ 2,354	\$ 2,638
Work-in process	327	408
Finished products	8,339	13,642
Less inventory reserve	(504)	(265)
	\$ 10,516	\$ 16,423
<b>Intangible assets, net:</b>		
Customer relationships	\$ 4,161	\$ 4,741
Technology	10,000	
Product registrations	3,883	4,227
Tradename	427	471
Covenants not to compete	62	32
Other	257	7
Less accumulated amortization	(4,538)	(2,694)
	\$ 14,252	\$ 6,784

The change in value of the intangible assets include the foreign currency fluctuation between the Chilean and Mexican pesos against the US dollar at September 30, 2011 and December 31, 2010. The increase in Technology and Other reflects the acquisition of CURNA, Inc. Refer to Note 5.

**NOTE 5 ACQUISITION AND INVESTMENTS***CURNA acquisition*

In January 2011, we acquired all of the outstanding stock of CURNA, Inc. ( CURNA ) in exchange for \$10.0 million in cash, plus \$0.6 million in liabilities, of which, \$0.5 million was paid at closing. In addition to the cash consideration, we have agreed to pay to the CURNA sellers a portion of any consideration we receive in connection with certain license, partnership or collaboration agreements we may enter into with third parties in the future relating to the CURNA technology, including, license fees, upfront payments, royalties and milestone payments. As a result, we recorded \$0.6 million, as contingent consideration for the future consideration. We will evaluate the contingent consideration on an ongoing basis and the changes in fair value will be recognized in earnings until the contingencies are resolved. CURNA was a privately held company based in Jupiter, Florida, engaged in the discovery of new drugs for the treatment of a wide variety of illnesses, including cancer, heart disease, metabolic disorders and a range of genetic anomalies.

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

(in thousands)	
Current assets (including cash of \$5)	\$ 38

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Fixed assets	21
Intangible assets	
Technology	10,000
Patents	290
Total intangible assets	10,290
Goodwill	828
Accounts payable and accrued expenses	(54)
Contingent consideration	(580)
Total purchase price	\$ 10,543

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We believe the estimated fair values assigned to the CURNA assets acquired and liabilities assumed are based on reasonable assumptions. However, the fair value estimates for the purchase price allocation may change during the allowable allocation period, which is up to one year from the acquisition date, if additional information becomes available that would require changes to our estimates.

### *Exakta-OPKO acquisition*

In February 2010, we acquired Exakta-OPKO (previously known as Pharmacos Exakta S.A. de C.V.), a privately-owned Mexican company engaged in the manufacture, marketing and distribution of ophthalmic and other pharmaceutical products for government and private markets since 1957. Pursuant to a purchase agreement we acquired all of the outstanding stock of Exakta-OPKO and real property owned by an affiliate of Exakta-OPKO for a total aggregate purchase price of \$3.5 million, of which an aggregate of \$1.5 million was paid in cash and \$2.0 million was paid in shares of our Common Stock, par value \$.01. In September 2010, we reduced the consideration paid by \$0.1 million in working capital adjustments per the purchase agreement. The number of shares to be issued was determined by the average closing price of our Common Stock as reported on the NYSE Amex for the ten trading days ending on February 12, 2010. A total of 1,371,428 shares of our Common Stock were issued in the transaction which were valued at \$2.0 million due to trading restrictions. A portion of the proceeds will remain in escrow for a period of time to satisfy indemnification claims.

### *Investments*

In August 2011, we made an investment in Neovasc Inc. ( Neovasc ) a medical technology company based in Vancouver, Canada, a Canadian publicly traded company. Neovasc is developing devices to treat cardiovascular diseases and is also a leading supplier of tissue components for the manufacturers of replacement heart valves. We invested \$2.0 million and received two million Neovasc common shares, and two-year warrants to purchase an additional one million shares for \$1.25 a share. We recorded the warrants at their estimated fair value using the Black-Scholes-Merton Model at \$0.7 million. We recorded an unrealized loss of \$0.1 million at September 30, 2011 related to these warrants to reflect the closing price decrease of Neovasc common stock. We also entered into an agreement with Neovasc to provide strategic advisory services to Neovasc as it continues to develop and commercialize its novel cardiac devices. In connection with the consulting agreement, Neovasc granted us 913,750 common stock options. The options were granted at (Canadian) \$1.00 per share and vest annually over three years. We valued the options using the Black-Scholes-Merton Model at \$0.8 million on the date of grant and will recognize the revenue over four years as other revenue. In addition, we recorded an unrecognized loss of \$0.1 million at September 30, 2011 related to these options to reflect the (Canadian) \$0.91 closing share price of Neovasc. Refer to Note 9.

In November 2010, we made an investment in Fabrus, LLC ( Fabrus ), a privately held early stage biotechnology company with next generation therapeutic antibody drug discovery and development capabilities. Fabrus is using its proprietary antibody screening and engineering approach to discover promising lead compounds against several important oncology targets. As of September 30, 2011, we hold approximately 13% of Fabrus' outstanding membership interests on a fully diluted basis. Our investment was part of a \$2.1 million financing for Fabrus and included other related parties. Refer to Note 9.

Effective September 21, 2009, we entered into an agreement pursuant to which we invested \$2.5 million in cash in Cocrysal Discovery, Inc., a privately held biopharmaceutical company ( Cocrysal ). Cocrysal is focused on the discovery and development of novel antiviral drugs using a combination of protein structure-based approaches. As of September 30, 2011 we hold approximately 16% of Cocrysal on a fully diluted basis. Refer to Note 9.

On June 10, 2009, we entered into a stock purchase agreement with Sorrento Therapeutics, Inc. ( Sorrento ), a publicly held company with a technology for generating fully human monoclonal antibodies, pursuant to which we invested \$2.3 million in Sorrento. OPKO owns approximately 59,015,257 shares of Sorrento common stock, or approximately 26% of Sorrento's total outstanding common stock at September 30, 2011. The closing stock price for Sorrento's common stock, a thinly traded stock, as quoted on the over-the-counter markets was \$0.23 per share on September 30, 2011. Refer to Note 9.

### *Rolapitant license*

In December 2010, we entered into a license agreement (the TESARO License ) with TESARO, Inc. ( TESARO ) granting TESARO exclusive rights to the development, manufacture, commercialization and distribution of rolapitant and a related compound. Under the terms of the TESARO License, we are eligible for payments of up to \$121.0 million, including an up-front payment of \$6.0 million, which was received in December 2010, and additional payments based upon achievement of specified regulatory and commercialization milestones. In addition, TESARO will pay us double digit tiered royalties on sales of licensed product. We will share future profits from the commercialization of licensed products in Japan with TESARO and we will have an option to market the products in Latin America. In connection with the TESARO License, we also acquired an equity position in TESARO. We recorded the equity position at \$0.7 million, the estimated fair value based on a

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discounted cash flow model. In June 2011, TESARO completed an equity financing and as such, is no longer a variable interest entity as it has sufficient resources to carry out its principal activities without additional subordinated financial support.

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In accounting for the TESARO License, we determined that we did not have any continuing involvement in the development of rolapitant or any other future performance obligations and, as a result, recognized the \$6.0 million up-front payment and the \$0.7 million equity position as license revenue during the year ended December 31, 2010.

Pursuant to an asset purchase agreement with Schering-Plough Corporation ( Schering ), we acquired rolapitant and other assets relating to Schering s neurokinin-1 ( NK-1 ) receptor antagonist program on October 12, 2009 (the Schering Agreement ). Under the terms of the Schering Agreement, we paid Schering \$2.0 million in cash upon closing and agreed to pay up to an additional \$27.0 million upon certain development milestones. Rolapitant, the lead product in the NK-1 program, successfully completed Phase II clinical testing for prevention of nausea and vomiting related to cancer chemotherapy and surgery, and other indications. Development of rolapitant and the other assets had been stopped at the time of our acquisition and there were no ongoing clinical trials. We recorded \$2.0 million as in-process research and development expense upon our acquisition.

*Variable interest entities*

We have determined that we hold variable interests in two entities, Fabrus and CoCrystal. We made this determination as a result of our assessment that they do not have sufficient resources to carry out their principal activities without additional subordinated financial support.

In order to determine the primary beneficiary of Cocystal and Fabrus, we evaluated our investment as well as our investment combined with a related party group to identify who had the most power to control each entity and who received the largest benefits (or absorbed the most losses) from each entity. The related party group when considering our investment in Cocystal includes OPKO and the Frost Group, LLC (the Frost Group ). The Frost Group members include Frost Gamma Investments Trust, of which Phillip Frost, MD, our Chairman of our Board of Directors and Chief Executive Officer, is the sole trustee (the Gamma Trust ), 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. As of September 30, 2011 we own approximately 16% of Cocystal and members of the Frost Group own approximately 42% of Cocystal s voting stock on an as converted basis, including 39% held by the Gamma Trust. Dr. Frost, Mr. Rubin, and Dr. Hsiao currently serve on the Board of Directors of Cocystal and represent 50% of its board. The Gamma Trust can significantly influence Cocystal through its board representation and voting power. As such, we have determined that the Gamma Trust is the primary beneficiary within the related party group.

The related party group when considering our investment in Fabrus includes OPKO and the Gamma Trust, Hsu Gamma Investment, L.P., of which Jane Hsiao is the general partner ( Hsu Gamma ), and the Richard Lerner Family Trust. Drs. Frost, Hsiao and Lerner are all members of our Board of Directors. As of September 30, 2011, we own approximately 13% of Fabrus and Drs. Frost, Hsiao and Lerner own 24% of Fabrus voting stock on an as converted basis, including 16% held by the Gamma Trust. Drs. Frost and Hsiao currently serve on the Board of Managers of Fabrus and represent 40% of its board. The Gamma Trust can significantly influence the success of Fabrus through its board representation and voting power. As such, we have determined that the Gamma Trust is the primary beneficiary within the related party group. Because we have the ability to exercise significant influence over Cocystal s and Fabrus operations through our related party affiliates, we account for our investments in Cocystal and Fabrus, under the equity method.

We have not provided financial or other support to the variable interest entities other than those associated with our original investments in Cocystal and Fabrus and we are not obligated to provide ongoing financial support to them.



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The following table reflects our maximum exposure to each of our investments:

Investee name	(in thousands)	Accounting method
Sorrento (2009)	\$ 2,300	Equity method
Cocrystal (2009)	2,500	VIE, equity method
Fabrus (2010)	650	VIE, equity method
TESARO (2010)	731	Cost method
NEOVASC (2011)	2,013	Equity method, Cost (warrants)
Less accumulated losses in investees	(2,242)	
Unrealized loss	(90)	
Total	\$ 5,862	

**NOTE 6 DISCONTINUED OPERATIONS**

In September 2011, we announced that we entered into an agreement with OPTOS, Inc., a subsidiary of Optos plc (collectively OPTOS) to sell our ophthalmic instrumentation business. Upon closing in October 2011, we received \$17.5 million of cash and we will receive royalties up to \$22.5 million on future sales. We anticipate recording a gain in connection with the sale.

The assets and liabilities related to our instrumentation business have identifiable cash flows that are independent of the cash flows of other groups of assets and liabilities and we will not have a significant continuing involvement with the related products beyond one year after the closing of the transactions. Therefore, the accompanying Condensed Consolidated Balance Sheets report the assets and liabilities related to our instrumentation business as discontinued operations in all periods presented, and the results of operations related to our instrumentation business have been classified as discontinued operations in the accompanying Condensed Consolidated Statements of Operations for all periods presented.

The following table presents the major classes of assets and liabilities that have been presented as assets of discontinued operations and liabilities of discontinued operations in the accompanying Condensed Consolidated Balance Sheets:

In thousands	September 30, 2011	December 31, 2010
Trade accounts receivable, net	\$ 650	\$ 1,461
Inventories, net	4,427	3,534
Other current assets	202	103
Total current assets	5,279	5,098
Property, plant and equipment, net	94	140
Intangible assets, net	2,835	3,180
Total assets of discontinued operations	\$ 8,208	\$ 8,418
Trade accounts payable	\$ 299	\$ 690
Accrued expenses and other liabilities	1,161	2,370
Total liabilities of discontinued operations	\$ 1,460	\$ 3,060

The following table presents summarized financial information for the discontinued operations presented in the Condensed Consolidated Statements of Operations:

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(in thousands, except per share amounts)	For the three months ended September 30,		For the nine months ended September 30,	
	2011	2010	2011	2010
Total revenue	\$ 730	\$ 1,922	\$ 4,142	\$ 6,714
Operating loss	(1,481)	(2,522)	(2,819)	(4,460)
Loss before provision for income taxes	(1,487)	(2,522)	(2,841)	(4,462)
Net loss	(1,487)	(2,522)	(2,841)	(4,462)
Loss per share from discontinued operations, basic and diluted	\$ (0.00)	\$ (0.01)	\$ (0.01)	\$ (0.02)

**Table of Contents****NOTE 7 FAIR VALUE MEASUREMENTS**

We record fair value at an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. We utilize a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

As of September 30, 2011, we held money market funds and treasury securities that qualify as cash equivalents, marketable securities that consist of treasury securities, forward contracts for inventory purchases (Refer to Note 8) and contingent consideration related to the acquisition of CURNA (Refer to Note 5) that are required to be measured at fair value on a recurring basis. As of September 30, 2011, we held money market funds and treasury securities totaling \$55.7 million, including \$10.0 million of treasury securities maturing October 13, 2011, that are required to be measured at fair value on a recurring basis. In addition, we held \$30.2 million of US Treasury Notes. Both the \$10.0 million of treasury securities and the \$30.2 million of US Treasury Notes are recorded at amortized cost, which reflects their approximate fair value. The carrying value of our other assets and liabilities approximates their fair value due to their short-term nature. In addition, in connection with our investment in Neovasc as well as entering into our consulting agreement with Neovasc, we record our options and warrants at fair value. Refer to Note 5.

Any future fluctuation in fair value related to these instruments that is judged to be temporary, including any recoveries of previous write-downs, would be recorded in accumulated other comprehensive income or loss. If we determine that any future valuation adjustment was other-than-temporary, we would record a charge to the consolidated statement of operations as appropriate.

Our financial assets and liabilities measured at fair value on a recurring basis are as follows:

(in thousands)	Fair value measurements as of September 30, 2011				Total
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)		
<b>Assets:</b>					
Money market funds	\$ 45,709	\$	\$		\$ 45,709
Forward contracts		183			183
US Treasury Notes		30,182			30,182
US Treasury securities	10,000				10,000
Neovasc common stock options		736			736
Neovasc common stock warrants		564			564
<b>Total assets</b>	<b>\$ 55,709</b>	<b>\$ 31,665</b>	<b>\$</b>		<b>\$ 87,374</b>
<b>Liabilities:</b>					
CURNA contingent considerations	\$	\$	\$ 580		\$ 580
<b>Total liabilities</b>	<b>\$</b>	<b>\$</b>	<b>\$ 580</b>		<b>\$ 580</b>

**NOTE 8 DERIVATIVE CONTRACTS**

We enter into foreign currency forward exchange contracts to cover the risk of exposure to exchange rate differences arising from inventory purchases on letters of credit. Under these forward contracts, for any rate above or below the fixed rate, we receive or pay the difference between the spot rate and the fixed rate for the given amount at the settlement date.

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We record derivative financial instruments on our balance sheet at their fair value as an accrued expense and the changes in the fair value are recognized in our results from operations in other expense net when they occur, the only exception being derivatives that qualify as hedges. To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the

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hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2011, the forward contracts did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in fair values in income.

The outstanding contracts at September 30, 2011, have been recorded at fair value, and their maturity details are as follows:

(in thousands)			
Days until maturity	Contract value	Fair value at September 30, 2011	Unrealized gain
0 to 30	\$ 708	\$ 646	\$ 62
31 to 60	1,060	962	98
61 to 90	46	41	5
91 to 120	55	50	5
121 to 180	147	134	13
More than 180			
<b>Total</b>	<b>\$ 2,016</b>	<b>\$ 1,833</b>	<b>\$ 183</b>

**NOTE 9 RELATED PARTY TRANSACTIONS**

On August 17, 2011, we made an investment in Neovasc Inc. a medical technology company. Refer to Note 5. Dr. Frost and other members of OPKO management are shareholders of Neovasc. Prior to the investment, Dr. Frost beneficially owned approximately 36% of Neovasc, Dr. Jane Hsiao owned approximately 6%, and each of Dr. Uppaluri and Mr. Rubin owned less than 1%. Dr. Jane Hsiao and Steven Rubin also serve on the board of directors for Neovasc.

On March 14, 2011, we issued 27,000,000 shares of our Common Stock. Refer to Note 12. The 27,000,000 shares of our Common Stock issued include an aggregate of 3,733,000 shares of our Common Stock purchased by the Gamma Trust and Hsu Gamma at the public offering price. The Gamma Trust purchased an aggregate of 3,200,000 shares for approximately \$12 million, and Hsu Gamma purchased an aggregate of 533,000 shares for approximately \$1.9 million. Jefferies & Company, Inc. and J.P. Morgan Securities LLC acted as joint book-running managers for the offering. UBS Investment Bank and Lazard Capital Markets LLC acted as co-lead managers for the offering and Ladenburg Thalmann & Co. Inc., a subsidiary of Ladenburg Thalmann Financial Services Inc., acted as co-manager for the offering. Dr. Frost is the Chairman of the Board of Directors and principal shareholder of Ladenburg Thalmann Financial Services Inc.

On January 28, 2011, we entered into a definitive agreement with CURNA and each of CURNA's stockholders and optionholders, pursuant to which we agreed to acquire all of the outstanding stock of CURNA in exchange for \$10.0 million in cash, plus \$0.6 million in liabilities, of which \$0.5 million was paid at closing. At the time of the transaction, The Scripps Research Institute (TSRI) owned approximately 4% of CURNA. Dr. Frost serves as Trustee for TSRI and Richard Lerner is its President.

We have an unutilized \$12.0 million line of credit with the Frost Group. On June 2, 2010 we repaid all amounts outstanding on the line of credit including \$12 million in principal and \$4.1 million in interest. The line of credit, which previously expired on January 11, 2011, was renewed on February 22, 2011 until March 31, 2012 on substantially the same terms as those in effect at the time of expiration. We have the ability to draw funds under the line of credit until its expiration in March 2012. We are obligated to pay interest upon maturity, capitalized quarterly, on outstanding borrowings under the line of credit at an 11% annual rate. The line of credit is collateralized by all of our U.S. personal property except our intellectual property.

In November 2010, we made an investment in Fabrus, a privately held early stage biotechnology company with next generation therapeutic antibody drug discovery and development capabilities. In exchange for the investment, we acquired approximately 13% of Fabrus' outstanding membership interests on a fully diluted basis. Our investment was part of a \$2.1 million financing for Fabrus. Other investors participating in the financing include the Gamma Trust and Hsu Gamma. In connection with the financing, Drs. Frost and Hsiao joined the Fabrus Board of Managers. Dr. Richard Lerner, a director of the Company, owns approximately 5% of Fabrus. Vaughn Smider, Founder and CEO of Fabrus, is an Assistant Professor at TSRI. Dr. Frost serves as a Trustee for TSRI, and Richard Lerner serves as its President.

On July 20, 2010, we entered into a use agreement with TRSI for approximately 1,100 square feet of space in Jupiter, Florida to house our molecular diagnostics operations. Pursuant to the terms of the use agreement, which is



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effective as of November 1, 2009, gross rent is approximately \$40 thousand per year for a two-year term which may be extended upon mutual agreement for one additional year. In June 2011, the Company entered into a letter agreement with TSRI pursuant to which it licensed approximately 120 square feet of additional space for three months on substantially the same terms as the use agreement.

On June 1, 2010, the Company entered into a cooperative research and development agreement with Academia Sinica in Taipei, Taiwan ( Academia Sinica ), for pre-clinical work for a compound against various forms of cancer. Dr. Alice Yu, a member of our Board of Directors, is a Distinguished Research Fellow and Associate Director at the Genomics Research Center, Academia Sinica ( Genomics Research Center ). In connection with the agreement, we are required to pay Academia Sinica approximately \$0.2 million over the term of the agreement.

Effective March 5, 2010, the Frost Group assigned two license agreements with Academia Sinica to the Company. The license agreements pertain to alpha-galactosyl ceramide analogs and their use as immunotherapies and peptide ligands in the diagnosis and treatment of cancer. In connection with the assignment of the two licenses, the Company agreed to reimburse the Frost Group for the licensing fees previously paid by the Frost Group to Academia Sinica in the amounts of \$50 thousand and \$75 thousand, respectively, as well as reimbursement of certain expenses of \$50 thousand.

Effective September 21, 2009, we entered into an agreement pursuant to which we invested \$2.5 million in Cocrystal in exchange for 1,701,723 shares of Cocrystal's Convertible Series A Preferred Stock. A group of investors, led by the Frost Group (the CoCrystal Investors ), previously invested \$5 million in Cocrystal, and agreed to invest an additional \$5 million payable in two equal installments in September 2009 and March 2010. As a result of an amendment to the CoCrystal Investors agreements dated June 9, 2009, OPKO, rather than the CoCrystal Investors, made the first installment investment (\$2.5 million) on September 21, 2009. Refer to Note 5.

On July 20, 2009, we entered into a worldwide exclusive license agreement with Academia Sinica in Taipei, Taiwan, for a new technology to develop protein vaccines against influenza and other viral infections. Dr. Alice Yu, a member of our Board of Directors, is a Distinguished Research Fellow and Associate Director at the Genomics Research Center. In connection with the license, the Company paid to Academia Sinica an upfront licensing fee and agreed to pay royalties and other payments on the occurrence of certain development milestones.

On June 16, 2009, we entered into an agreement to lease approximately 10,000 square feet of space in Hialeah, Florida to house manufacturing and service operations for our ophthalmic instrumentation business (the Hialeah Facility ) from an entity controlled by Drs. Frost and Hsiao. Effective as of July 1, 2011, the lease was amended to include an additional 5,000 square feet of space at the same rate per square foot as was then in effect under the lease. Following the amendment, gross rent payable under the lease is \$0.2 million per year. Upon the closing of the sale of the Company's instrumentation business to Optos, the Company assigned the lease to Optos.

On June 10, 2009, we entered into a stock purchase agreement with Sorrento, pursuant to which we invested \$2.3 million in Sorrento. Refer to Note 5. In exchange for the investment, we acquired approximately one-third of the outstanding common shares of Sorrento and received a fully-paid, exclusive license to the Sorrento antibody library for the discovery and development of therapeutic antibodies in the field of ophthalmology. On September 21, 2009, Sorrento entered into a merger transaction with Quikbyte Software, Inc. Prior to the merger transaction, certain investors, including Dr. Frost and other members of OPKO management, made an investment in Quikbyte. Dr. Richard Lerner, a member of our Board of Directors, serves as a consultant and scientific advisory board member to Sorrento and owns less than one percent of its shares.

In November 2007, we entered into an office lease with Frost Real Estate Holdings, LLC, an entity affiliated with Dr. Frost. 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. The lease provides for payments of approximately \$18 thousand per month in the first year increasing annually to \$24 thousand 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 was reduced to reflect a \$30 thousand credit for the costs of tenant improvements.

On September 19, 2007, we entered into an exclusive technology license agreement with Winston Laboratories, Inc. ( Winston ). On February 23, 2010, we provided Winston notice of termination of the license agreement, and the agreement terminated on May 24, 2010. Previously, members of the Frost Group beneficially owned approximately 30% of Winston Pharmaceuticals, Inc., and Dr. Uppaluri, our Chief Financial Officer, served as a member of Winston's board. Effective May 19, 2010, the members of the Frost Group sold 100% of Winston's capital stock beneficially owned by them to an entity whose members include Dr. Joel E. Bernstein, the President

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and Chief Executive Officer of Winston. As consideration for the sale, the Frost Group members received an aggregate of \$789,500 in cash and non-recourse promissory notes in the aggregate principal amount of \$10,263,500. Dr. Uppaluri resigned from the Winston board effective May 19, 2010.

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost in an amount equal to the cost of a first class airline ticket between the travel cities for each executive, including Dr. Frost, traveling on the airplane for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive; nor do we pay for any other fixed or variable operating costs of the airplane. For the three and nine months ended September 30, 2011, we reimbursed Dr. Frost approximately \$14 thousand and \$127 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2010, we reimbursed Dr. Frost approximately \$5 thousand and \$30 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

**NOTE 10 COMMITMENTS AND CONTINGENCIES**

In connection with our acquisition of CURNA, we agreed to pay a portion of future consideration to the CURNA sellers if we license or partner the CURNA technology with a third party including, license fees, upfront payments, royalties and milestone payments. As a result, we recorded \$0.6 million, as contingent consideration for the future consideration. Refer to Note 5.

On January 7, 2010, we received a letter from counsel to Nidek Co., Ltd. ( Nidek ) alleging that Ophthalmic Technologies, Inc. ( OTI ) or OPKO breached its service obligations to Nidek under the Service Agreement between OTI, Nidek and Newport Corporation, dated December 29, 2006, and the Service Agreement by and between Nidek and OTI, dated the same date. We entered into a settlement agreement in April 2011 which resolved all disputes between the Company and Nidek and released us from any future service obligation to Nidek. The settlement did not have a material impact on our results of operations or financial condition.

On May 6, 2008, we completed the acquisition of Vidus Ocular, Inc. ( Vidus ). Pursuant to a Securities Purchase Agreement with Vidus, each of its stockholders, and the holders of convertible promissory notes issued by Vidus, we acquired all of the outstanding stock and convertible debt of Vidus in exchange for (i) the issuance and delivery at closing of 658,080 shares of our Common Stock (the Closing Shares ); (ii) the issuance of 488,420 shares of our Common Stock to be held in escrow pending the occurrence of certain development milestones (the Milestone Shares ); and (iii) the issuance of options to acquire 200,000 shares of our Common Stock. Additionally, in the event that the stock price for our Common Stock at the time of receipt of approval or clearance by the U.S. Food & Drug Administration of a pre-market notification 510(k) relating to the Aquashunt is not at or above a specified price, we will be obligated to issue an additional 413,850 shares of our Common Stock.

We are a party to other 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.

**NOTE 11 SEGMENTS**

We currently manage our operations in one reportable segment, pharmaceutical. The pharmaceutical segment consists of two operating segments, our (i) pharmaceutical research and development segment which is focused on the research and development of pharmaceutical products, diagnostic tests and vaccines, and (ii) the pharmaceutical operations we acquired in Chile and Mexico through the acquisition of OPKO Chile and Exakta-OPKO. There are no inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

In connection with the classification of our ophthalmic instrumentation business as discontinued operations, we have reclassified activities related to our Aquashunt development program to our pharmaceutical research and development operating segment.



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Information regarding our geographic activities is as follows:

(in thousands)	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2011	2010	2011	2010
Product sales				
Chile	\$ 5,356	\$ 4,517	\$ 17,545	\$ 13,711
Mexico	1,404	1,161	4,568	2,551
All others				
	\$ 6,760	\$ 5,678	\$ 22,113	\$ 16,262

During the three and nine months ended September 30, 2011, our largest customer represented approximately 20% and 18% of our revenue from continuing operations, respectively. As of September 30, 2011, our largest customer represented approximately 35% of our accounts receivable balance from continuing operations. During the three months ended September 30, 2010, our two largest customers represented approximately 16% and 10%, respectively, of revenue from continuing operations. During the nine months ended September 30, 2010, our two largest customers represented 12% and 10% of our revenue from continuing operations. As of December 31, 2010, two customers represented 35% and 12%, respectively, of our accounts receivable balance from continuing operations.

**NOTE 12 COMMON STOCK ISSUANCE, REPURCHASE AND SERIES A PREFERRED STOCK REDEMPTION**

On March 14, 2011, we issued 27,000,000 shares of our Common Stock in a public offering at a price of \$3.75 per share. We also granted the underwriters a 30-day option to purchase up to an additional 4,050,000 shares of our Common Stock to cover over-allotments, if any. On March 15, 2011, representatives for the underwriters provided us notice that the underwriters exercised a portion of their 4,050,000 share over-allotment option for 2,397,029 additional shares of our Common Stock.

The following table reflects the proceeds received from the issuance of shares:

(in thousands, except share amounts)	Shares	Dollars
Original issuance	27,000,000	\$ 101,250
Over-allotment	2,397,029	8,989
<b>Total</b>	<b>29,397,029</b>	<b>110,239</b>
Underwriters discount and commissions <sup>(1)</sup>	5.5% on 24,064,029 shares	(4,963)
Offering expenses		(448)
Net proceeds		\$ 104,828

<sup>(1)</sup> The underwriters did not receive any underwriting discount or commissions on the sale of 5,333,000 shares of common stock to entities associated with certain stockholders, including two of our directors and executive officers. Refer to Note 9.

On June 20, 2011, we repurchased 2,398,740 shares of our Common Stock for an aggregate purchase price of \$7.8 million through a privately negotiated transaction with an early investor in Acuity Pharmaceuticals, Inc., a predecessor company of ours.

On June 3, 2011, we redeemed all outstanding shares of our Series A Preferred Stock for an aggregate redemption price of \$1.8 million, including accrued dividends.

**NOTE 13 SUBSEQUENT EVENTS**

## Edgar Filing: Opko Health, Inc. - Form 10-Q

On October 11, 2011, we completed the sale of our ophthalmic instrumentation businesses to Optos. Refer to Note 6.

On October 13, 2011, we acquired Claros Diagnostics, Inc. ( Claros ) pursuant to an agreement and plan of merger. We paid \$10.0 million in cash, subject to certain set-offs and deductions, and \$20.0 million in shares of our common stock (the Stock Consideration ), based on the average closing sales price per share of our Common Stock

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as reported by the New York Stock Exchange for the ten trading days immediately preceding the closing date of the Merger, or \$4.45 per share. Pursuant to the merger agreement, \$5.0 million of the Stock Consideration is held in a separate escrow account to secure the indemnification obligations of Claros under the Claros Merger Agreement. In addition, the merger agreement provides for the payment of up to an additional \$19.125 million in shares of our Common Stock upon and subject to the achievement of certain milestones.

On November 3, 2011, our Board of Directors declared a cash dividend to all Series D Preferred Stockholders as of November 3, 2011. The total cash dividend is expected to be approximately \$4.7 million.

We have reviewed all subsequent events and transactions that occurred after the date of our September 30, 2011 condensed consolidated balance sheet date, through the time of filing this Quarterly Report on Form 10-Q.

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

**OVERVIEW**

*You should read this discussion together with the condensed consolidated financial statements, related Notes, and other financial information included elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2010 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part II, Item 1A of our Form 10-K for the year ended December 31, 2010. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.*

We are a multi-national pharmaceutical and diagnostics company that seeks to establish industry-leading positions in large and rapidly growing medical markets by leveraging our discovery, development and commercialization expertise and our novel and proprietary technologies. Our current focus is on conditions with major unmet medical needs. We are developing a range of solutions to diagnose, treat and prevent various conditions, including molecular diagnostics tests, proprietary pharmaceuticals and vaccines. We plan to commercialize these solutions on a global basis in large and high growth markets, including emerging markets. We have already established emerging markets pharmaceutical platforms in Chile and Mexico, which are delivering revenue and which we expect to deliver cash flow and facilitate future market entry for our products currently in development. We also actively explore opportunities to acquire complementary pharmaceuticals, compounds, technologies, and businesses.

We expect to incur substantial losses as we continue the development of our product candidates, continue our other research and development activities, and establish a sales and marketing infrastructure in anticipation of the commercialization of our diagnostic and pharmaceutical product candidates. We currently have limited commercialization capabilities, and it is possible that we may never successfully commercialize any of our diagnostic and pharmaceutical product candidates. We do not currently generate revenue from any of our diagnostic and pharmaceutical product candidates. Our research and development activities are budgeted to expand over a period of 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 may 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 in the future when needed on acceptable terms, or at all.

**RECENT DEVELOPMENTS**

On October 13, 2011, we acquired Claros Diagnostics, Inc. ("Claros") pursuant to an agreement and plan of merger. We paid \$10.0 million in cash, subject to certain set-offs and deductions, and \$20.0 million in shares of our common stock (the "Stock Consideration"), based on the average closing sales price per share of our Common Stock as reported by the New York Stock Exchange for the ten trading days immediately preceding the closing date of the Merger, or \$4.45 per share. Pursuant to the merger agreement, \$5.0 million of the Stock Consideration is held in a separate escrow account to secure the indemnification obligations of Claros under the Claros Merger Agreement. In addition, the merger agreement provides for the payment of up to an additional \$19.125 million in shares of our Common Stock upon and subject to the achievement of certain milestones.

On September 21, 2011, we entered into an agreement to sell our ophthalmic instrumentation business to OPTOS, Inc., a subsidiary of Optos plc, (collectively, "OPTOS") a medical technology company engaged in the design, development, manufacture and marketing of devices to image the retina of the eye. We received \$17.5 million in cash upon closing, which occurred on October 11, 2011 and OPTOS acquired our worldwide activities for the development and commercialization of ophthalmic diagnostic imaging systems. In addition, OPTOS will pay us up to \$22.5 million in future royalties on future sales.

In September 2011, we transferred the listing of our Common Stock from the NYSE Amex to the New York Stock Exchange.

On August 17, 2011, we made a \$2.0 million investment in Neovasc Inc. ("Neovasc") a medical technology company based in Vancouver, Canada. Neovasc is developing unique devices to treat cardiovascular diseases and is also a leading supplier of tissue components for the manufacturer of replacement heart valves. We received two million Neovasc common shares, and two-year warrants to purchase an additional one million shares for \$1.25 a share. We have also entered into an agreement with Neovasc to provide strategic advisory services to Neovasc as it continues to develop and commercialize its novel cardiac devices.

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**RESULTS OF OPERATIONS**

**FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010**

*Revenue.* Revenue for the three months ended September 30, 2011, was \$6.8 million, compared to \$5.7 million for the comparable 2010 period. The increase in revenue during the three months ended September 30, 2011 is due to revenue from our Chilean and Mexican pharmaceutical businesses as we increase the customer base at those businesses.

*Gross margin.* Gross margin for the three months ended September 30, 2011, was \$2.8 million compared to \$2.3 million for the comparable period of 2010. Gross margin for the three months ended September 30, 2011, increased primarily as a result of the increased gross margin generated by our pharmaceutical businesses in Chile and Mexico.

*Selling, general and administrative expense.* Selling, general and administrative expense for the three months ended September 30, 2011, was \$4.3 million compared to \$4.4 million of expense for the comparable period of 2010. The increase in selling, general and administrative expenses is primarily the result of increased professional fees and personnel expenses, partially offset by decreased equity based compensation. Selling, general and administrative expenses during the three months ended September 30, 2011 and 2010 primarily include personnel expenses, including equity-based compensation expense of \$0.5 million and \$1.2 million, respectively, and professional fees.

*Research and development expense.* Research and development expense during the three months ended September 30, 2011 and 2010, was \$3.3 million and \$1.5 million, respectively. The increase in research and development expense primarily related to our molecular diagnostics development programs and development of the technology acquired from CURNA including increased personnel expenses. The three months ended September 30, 2011 and 2010, include equity-based compensation expense of \$1.3 million and \$0.2 million, respectively.

*Other operating expenses.* Other operating expenses were \$0.9 million and \$0.6 million, respectively, for the three months ended September 30, 2011 and September 30, 2010. Other operating expenses primarily include the amortization of intangible assets. Amortization expense during the three months ended September 30, 2011 increased from the 2010 comparable period as a result of the 2011 period including amortization expense related to the CURNA intangible assets acquired in January 2011.

*Other income and expenses.* Other expense was \$0.7 million for the three months ended September 30, 2011 compared to \$0.3 million for the comparable 2010 period. Other income and expense primarily consists of interest earned on our cash and cash equivalents, offset by increased interest expense on our lines of credit in Chile and foreign currency expense. Other expense during the 2010 period primarily reflects the interest incurred on our lines of credit in Chile and foreign exchange.

*Income taxes.* Our income tax provision reflects the income tax payable in Chile and Mexico. We have recorded a full valuation allowance against our deferred tax assets in the U.S.

*Discontinued operations.* Loss from discontinued operations was \$1.5 million for the three months ended September 30, 2011 compared to \$2.5 million for the three months ended September 30, 2010. Loss from discontinued operations decreased during the 2011 period from the 2010 period as a result of decreased selling, general and administrative expenses as well as decreased amortization expense related to intangibles that were fully amortized in November 2010.

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**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2011 AND 2010**

*Revenue.* Revenue for the nine months ended September 30, 2011, was \$22.2 million, compared to \$16.3 million for the comparable 2010 period. The increase in revenue during the first nine months of 2011 is primarily due to revenue from our pharmaceutical businesses in Chile and Mexico. We acquired Exakta-OPKO in February 2010, and as a result, the 2010 period reflects revenue only after the acquisition occurred.

*Gross margin.* Gross margin for the nine months ended September 30, 2011, was \$9.1 million compared to \$6.1 million for the comparable period of 2010. Gross margin for the nine months ended September 30, 2011, increased from the 2010 period primarily as a result of the increased gross margin generated by our pharmaceutical businesses in Chile and Mexico.

*Selling, general and administrative expense.* Selling, general and administrative expense for the nine months ended September 30, 2011, was \$14.1 million compared to \$12.8 million of expense for the comparable period of 2010. The increase in selling, general and administrative expenses is primarily the result of increased warehousing and distribution costs for our Chilean operations, and a full period of selling, general and administrative expenses for our operations in Mexico. Selling, general and administrative expenses during the first nine months of 2011 and 2010 primarily include personnel expenses, including equity-based compensation expense of \$2.2 million and \$3.4 million, respectively, and professional fees.

*Research and development expense.* Research and development expense during the nine months ended September 30, 2011 and 2010, was \$7.1 million and \$3.6 million, respectively. The increase in research and development expense primarily is the result of increased personnel expenses including equity based compensation expense. The nine months ended September 30, 2011 and 2010, include equity-based compensation expense of \$3.0 million and \$0.7 million, respectively. During the nine months ended September 30, 2011, research and development expense primarily consisted of activities related to our molecular diagnostics development program and development of the technology acquired from CURNA. Research and development expense for the nine month period ended September 30, 2010 primarily included activities related to our rolapitant development program, which we out-licensed in December 2010, as well as our molecular diagnostics development programs.

*Other operating expenses.* Other operating expense was \$2.6 million for the nine months ended September 30, 2011 compared to \$1.6 million for the nine months ended September 30, 2010. Other operating expenses primarily include the amortization of intangible assets. Amortization expense during the nine months ended September 30, 2011 increased from the comparable period of 2010 as a result of amortization expense of the CURNA intangible assets acquired in January 2011.

*Other income and expenses.* Other expense, net was \$0.8 million for the first nine months of 2011 compared to other expense, net of \$1.0 million for the comparable 2010 period. Other income and expenses primarily consists of interest earned on our cash and cash equivalents offset by interest expense on our Chilean lines of credit and foreign currency expense for the 2011 period, compared to the 2010 period which primarily reflects the interest incurred on our line of credit with The Frost Group LLC (the "Frost Group"). On June 2, 2010, we repaid all amounts outstanding on the Frost Group line of credit including \$12.0 million in principal and \$4.1 million in interest. The Frost Group members include a trust controlled by Dr. 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.

*Income taxes.* Our income tax provision reflects the income tax payable in Chile and Mexico. We have recorded a full valuation allowance against our deferred tax assets in the U.S.

*Discontinued operations.* Loss from discontinued operations was \$2.8 million for the nine months ended September 30, 2011 compared to \$4.5 million for the nine months ended September 30, 2010. Loss from discontinued operations decreased during the 2011 period from the 2010 period as a result of decreased selling, general and administrative expenses, including a settlement with one of our international distributors as well as decreased amortization expense related to intangibles that were fully amortized in November 2010.

**LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2011, we had cash, cash equivalents and marketable securities of approximately \$87.4 million. Cash used in operations during 2011 primarily reflects expenses related to research and development activities,

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selling, general and administrative activities related to our corporate operations, as well as our operations in Chile and Mexico. Since our inception, we have not generated sufficient gross margins to offset our operating and other expenses and our primary source of cash has been from the sale of our stock and credit facilities available to us.

On November 3, 2011, our Board of Directors declared a cash dividend to all Series D Preferred Stockholders as of November 3, 2011. The total cash dividend is expected to be approximately \$4.7 million.

On October 13, 2011, we acquired Claros Diagnostics, Inc. ( Claros ) pursuant to an agreement and plan of merger. We paid \$10.0 million in cash, subject to certain set-offs and deductions, and \$20.0 million in shares of our common stock (the Stock Consideration ), based on the average closing sales price per share of our Common Stock as reported by the New York Stock Exchange for the ten trading days immediately preceding the closing date of the Merger, or \$4.45 per share. Pursuant to the merger agreement, \$5.0 million of the Stock Consideration is held in a separate escrow account to secure the indemnification obligations of Claros under the Claros Merger Agreement. In addition, the merger agreement provides for the payment of up to an additional \$19.125 million in shares of our Common Stock upon and subject to the achievement of certain milestones.

On September 21, 2011, we entered into an agreement to sell our ophthalmic instrumentation business to OPTOS, Inc., a subsidiary of Optos plc. (collectively, OPTOS ), a medical technology company engaged in the design, development, manufacture and marketing of devices to image the retina of the eye. At closing, which occurred on October 11, 2011, Optos acquired our worldwide activities for the development and commercialization of ophthalmic diagnostic imaging systems, and we received \$17.5 million in cash. In addition, OPTOS will pay us up to \$22.5 million in future royalties on future sales.

In August 2011, we made \$2.0 million investment in Neovasc Inc. ( Neovasc ) a medical technology company based in Vancouver, Canada, a Canadian publicly traded company. We received two million Neovasc common shares, and two-year warrants to purchase an additional one million shares for \$1.25 a share. We also entered into an agreement with Neovasc to provide strategic advisory services to Neovasc as it continues to develop and commercialize its novel cardiac devices.

On June 20, 2011, we repurchased 2,398,740 shares of our Common Stock for an aggregate purchase price of \$7.8 million through a privately negotiated transaction with an early investor in Acuity Pharmaceuticals, Inc., a predecessor company of ours.

On June 3, 2011, we redeemed all outstanding shares of our Series A Preferred Stock for an aggregate redemption price of \$1.8 million, including accrued dividends.

On March 14, 2011, we issued 27,000,000 shares of our Common Stock in a public offering at a price of \$3.75 per share. We also granted the underwriters a 30-day option to purchase up to an additional 4,050,000 shares of our Common Stock to cover over-allotments, if any. On March 15, 2011, representatives for the underwriters provided us notice that the underwriters exercised a portion of their 4,050,000 share over-allotment option for 2,397,029 additional shares of our Common Stock. We received approximately \$104.8 million, net, from the issuance of 29,397,029 shares of our Common Stock.

On January 31, 2011, we acquired all of the outstanding stock of CURNA in exchange for \$10.0 million in cash, plus \$0.6 million in liabilities, of which, \$0.5 million was paid at closing. In addition to the cash consideration, we have agreed to pay to the CURNA sellers a portion of any consideration we receive in connection with certain license, partnership or collaboration agreements we may enter into with third parties in the future relating to the CURNA technology, including, license fees, upfront payments, royalties and milestone payments. As a result, we recorded \$0.6 million, as contingent consideration for the future consideration. CURNA is engaged in the discovery of new drugs for the treatment of a wide variety of illnesses, including cancer, heart disease, metabolic disorders and a range of genetic anomalies.

We have outstanding lines of credit in the aggregate amount of \$12.5 million with nine financial institutions in Chile, of which, approximately \$3.5 million is unused. These lines of credit are used primarily as a source of working capital and for inventory purchases. The average interest rate on these lines of credit is approximately 7%. These lines of credit are short term and are generally due within three months. The highest balance at any time during the three months ended September 30, 2011, was \$14.7 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that this or other funding sources will be available to us on acceptable terms, or at all.

We currently have an unutilized \$12.0 million line of credit with the Frost Group. The line of credit, which previously expired on January 11, 2011, was renewed on February 22, 2011 on substantially the same terms as those in effect at the time of expiration. We are obligated to pay interest upon maturity, capitalized quarterly, on





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outstanding borrowings under the line of credit at an 11% annual rate, which is due March 31, 2012. The line of credit is collateralized by all of our U.S. based personal property except our intellectual property. As of September 30, 2011, there were no amounts outstanding under this line of credit.

We expect to incur losses from operations for the foreseeable future. We expect to incur substantial research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that selling, general and administrative expenses will also increase as we expand our sales, marketing and administrative staff and add infrastructure.

We believe the cash, cash equivalents, and marketable securities on hand at September 30, 2011 and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements will depend on a number of factors, including possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, and our success in developing markets for our product candidates. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs.

We intend to finance additional research and development projects, clinical trials and our future operations with a combination of available cash on hand, payments from potential strategic research and development, licensing and/or marketing arrangements, public offerings, private placements, debt financing and revenues from future product sales, if any. There can be no assurance, however, that additional capital will be available in the future to us on acceptable terms, or at all.

## **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

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

*Equity-based compensation.* We recognize equity based compensation as an expense in our financial statements and that cost is measured at the fair value of the award and expensed over their vesting period. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. We estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the Black-Scholes Model and allocate the resulting compensation expense over the corresponding requisite service period associated with each grant. The Black-Scholes Model requires the use of several variables to estimate the grant-date fair value of stock options including expected term, expected volatility, expected dividends and risk-free interest rate. We perform significant analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model. We also perform significant analyses to estimate forfeitures of equity-based awards. We are required to adjust our forfeiture estimates on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates may have a material impact on our Consolidated Financial Statements.

*Goodwill and intangible assets.* The allocation of the purchase price for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination.

Appraisals inherently require significant estimates and assumptions, including but not limited to, determining the timing and estimated costs to complete the in-process research and development projects, projecting regulatory approvals, estimating future cash flows, and developing appropriate discount rates. We believe the estimated fair values assigned to the CURNA assets acquired and liabilities assumed are based on reasonable assumptions. However, the fair value estimates for the purchase price allocation may change during the allowable allocation period, which is up to one year from the acquisition date, if additional information becomes available that would require changes to our estimates.



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*Allowance for doubtful accounts and revenue recognition.* Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Certain of our products are sold directly to end-users and require that we deliver, install and train the staff at the end-users' facility. As a result, we do not recognize revenue until the product is delivered, installed and training has occurred. Return policies in certain international markets for our medical device products provide for stringent guidelines in accordance with the terms of contractual agreements with customers. Our estimates for sales returns are based upon the historical patterns of products returned matched against the sales from which they originated, and management's evaluation of specific factors that may increase the risk of product returns. We analyze accounts receivable and historical bad debt levels, customer credit worthiness and current economic trends when evaluating the adequacy of the allowance for doubtful accounts using the specific identification method. Our reported net loss is directly affected by management's estimate of the collectability of accounts receivable. The allowance for doubtful accounts recognized in our consolidated balance sheets at September 30, 2011 and December 31, 2010 was \$0.3 million and \$0.3 million, respectively.

*Recent accounting pronouncements:* In May 2011, the Financial Accounting Standards Board ( FASB ) issued amended accounting guidance related to fair value measurements and disclosures with the purpose of converging the fair value measurement and disclosure guidance issued by the FASB and the International Accounting Standards Board. The guidance is effective for reporting periods beginning after December 15, 2011. The guidance includes amendments that clarify the intent of the application of existing fair value measurement requirements along with amendments that change a particular principle or requirement for fair value measurements and disclosures. We concluded that the new guidance will not have a material impact on our Condensed Consolidated Statements of Operations, Condensed Consolidated Balance Sheet, or related disclosures.

In June 2011, the FASB issued amended accounting guidance related to presentation of comprehensive income. The standards update is intended to help financial statement users better understand the causes of an entity's change in financial position and results of operation. It is effective for reporting periods beginning after December 15, 2011. The amendments eliminate the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The amendments require that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The guidance also requires that reclassification adjustments for items that are reclassified from other comprehensive income to net income be presented on the face of the financial statement where the components of net income and other comprehensive income are presented. Upon adoption, we will continue to present components of comprehensive income in our Consolidated Statements of Operations. These statements will include reclassification adjustments as required by the new guidance for all periods presented. Since this new guidance will affect disclosure requirements only, we have concluded that it will not have a material impact on our financial position or results of operations.

In September 2011, the FASB issued ASU to amend the guidance in the ASC related to *Intangibles - Goodwill and Other*. This amendment will provide us the option of performing a qualitative assessment before calculating the fair value of the reporting unit. If it is determined that the fair value of the reporting unit is more likely than not less than the carrying amount, on the basis of qualitative factors, the two-step impairment test would be required. The amendment is effective for annual and interim goodwill impairment tests performed for our 2012 fiscal year, with earlier adoption permitted. This ASU impacts the manner in which goodwill is assessed for impairment but does not change how goodwill is calculated or assigned to reporting units, nor does it revise the requirement to test goodwill annually for impairment. It also does not change the requirement to test goodwill for impairment between annual tests if there are indicators of impairment. This ASU has no effect on our financial condition, results of operations or cash flows.

### **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.

**Foreign Currency Exchange Rate Risk** Although we do not speculate in the foreign exchange market, we may from time to time manage exposures that arise in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. Certain firmly committed transactions are hedged with foreign exchange forward contracts. As exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. Both the exposed transactions and the hedging contracts are translated at current spot rates, with gains and losses included in earnings.

Our derivative activities, which consist of foreign exchange forward contracts, are initiated to hedge forecasted cash flows that are exposed to foreign currency risk. The foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity dates. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the consolidated statement of operations at maturity, and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. If the counterparties to the



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exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. We enter into these contracts with counterparties that we believe to be creditworthy and we do not enter into any leveraged derivative transactions. We had \$1.8 million in foreign exchange forward contracts outstanding at September 30, 2011, primarily to hedge Chilean-based operating cash flows against US dollars. If Chilean pesos were to strengthen in relation to the US dollar, our hedged foreign currency cash-flows expense would be offset by a loss on the derivative contracts, with a net effect of zero.

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.

**Interest Rate 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 treasury securities. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment. At September 30, 2011, we had cash, cash equivalents and marketable securities of \$87.4 million. The weighted average interest rate related to our cash and cash equivalents for the three months ended September 30, 2011 was 0%. As of September 30, 2011, the principal value of our credit lines was \$12.5 million, and have a weighted average interest rate of approximately 8% for the nine months then ended.

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

### **Item 4. Controls and Procedures**

#### ***Disclosure Controls and Procedures***

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer ( CEO ) and Chief Financial Officer ( CFO ), has evaluated the effectiveness of the Company's disclosure controls and procedures as defined in Securities and Exchange Commission ( SEC ) Rule 13a-15(e) as of September 30, 2011. Based on that evaluation, the CEO and CFO have concluded that the Company's disclosure controls and procedures are effective to ensure that information the Company is required to disclose in reports that it files or submits under the Securities Exchange Act is accumulated and communicated to management, including the CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure and is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms.

#### ***Changes to the Company's Internal Control Over Financial Reporting***

There have been no changes to the Company's internal control over financial reporting that occurred during the Company's third quarter of 2011 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

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**

There have been no material changes from the risk factors as previously disclosed in the Item 1A of the Company Annual Report on Form 10-K for the year ended December 31, 2010.



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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. (Removed and Reserved)**

**Item 5. Other Information**

None.

**Item 6. Exhibits.**

- Exhibit 1.1<sup>(6)</sup> Underwriting Agreement dated March 9, 2011, by and among OPKO Health, Inc., Jefferies & Company, Inc. and J.P. Morgan Securities LLC, as representatives for the underwriters named therein.
- Exhibit 2.1<sup>(1)</sup> Merger Agreement and Plan of Reorganization, dated as of March 27, 2007, by and among Acuity Pharmaceuticals, Inc., Froprix Corporation, eXegenics, Inc., e-Acquisition Company I-A, LLC, and e-Acquisition Company II-B, LLC.
- Exhibit 2.2<sup>(4)+</sup> Securities Purchase Agreement dated May 2, 2008, among Vidus Ocular, Inc., OPKO Instrumentation, LLC, OPKO Health, Inc., and the individual sellers and noteholders named therein.
- Exhibit 2.3<sup>(5)</sup> Purchase Agreement, dated February 17, 2010, among Ignacio Levy García and José de Jesús Levy García, Inmobiliaria Chapalita, S.A. de C.V., Pharmacos Exakta, S.A. de C.V., OPKO Health, Inc., OPKO Health Mexicana S. de R.L. de C.V., and OPKO Manufacturing Facilities S. de R.L. de C.V.
- Exhibit 2.4<sup>(7+)</sup> Agreement and Plan of Merger, dated January 28, 2011, among CURNA Inc., KUR, LLC, OPKO Pharmaceuticals, LLC, OPKO CURNA, LLC, and certain individuals named therein.
- Exhibit 2.5 Agreement and Plan of Merger, dated October 13, 2011, by and among OPKO Health, Inc., Claros Merger Subsidiary, LLC, Claros Diagnostics, Inc. and Ellen Baron, Marc Goldberg, and Michael Magliochetti on behalf of the Shareholder Representative Committee.
- Exhibit 3.1<sup>(2)</sup> Amended and Restated Certificate of Incorporation.
- Exhibit 3.2<sup>(3)</sup> Amended and Restated By-Laws.
- Exhibit 4.1<sup>(1)</sup> Form of Common Stock Warrant.
- Exhibit 10.1<sup>+</sup> Asset Purchase Agreement dated as of September 21, 2011, by and among Optos plc, Optos Inc., OPKO Health, Inc., OPKO Instrumentation, LLC, Ophthalmic Technologies, Inc., and OTI (UK) Limited.
- 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, 2011.
- 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, 2011.

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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, 2011.
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, 2011.
Exhibit 101*	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) Notes to Financial Statements, tagged as blocks of text.

+ Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.

\* As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of sections 11 and 12 of the Securities Act of 1933, as amended, or section 18 of the Securities Exchange Act of 1934, as amended.

(1) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 2, 2007, and incorporated herein by reference.

(2) Filed with the Company's Current Report on Form 8-A filed with the Securities and Exchange Commission on June 11, 2007, and incorporated herein by reference.

(3) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008 and incorporated herein by reference.

(4) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2008 for the Company's three-month period ended June 30, 2008, and incorporated herein by reference.

(5) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2010 for the Company's three-month period ended March 31, 2010, and incorporated herein by reference.

(6) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 10, 2011, and incorporated herein by reference.

(7) Filed with the Company's Quarterly Report on Form 10-Q/A filed with the Securities and Exchange Commission on July 5, 2011 for the Company's three-month period ended March 31, 2011, and incorporated herein by reference.



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**SIGNATURES**

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

Date: November 9, 2011

**OPKO Health, Inc.**

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

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Exhibit Number	Description
Exhibit 2.5	Agreement and Plan of Merger, dated October 13, 2011, by and among OPKO Health, Inc., Claros Merger Subsidiary, LLC, Claros Diagnostics, Inc. and Ellen Baron, Marc Goldberg, and Michael Magliochetti on behalf of the Shareholder Representative Committee.
Exhibit 10.1 <sup>+</sup>	Asset Purchase Agreement dated as of September 21, 2011, by and among Optos plc, Optos Inc., OPKO Health, Inc., OPKO Instrumentation, LLC, Ophthalmic Technologies, Inc., and OTI (UK) Limited.
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, 2011.
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<sup>+</sup> Certain confidential material contained in the document has been omitted and filed separately with the Securities and Exchange Commission.

<sup>\*</sup> As provided in Rule 406T of Regulation S-T, this information is furnished herewith and not filed for purposes of sections 11 and 12 of the Securities Act of 1933, as amended, or section 18 of the Securities Exchange Act of 1934, as amended.