

Opko Health, Inc.  
Form 10-Q  
August 08, 2016  
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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 June 30, 2016.

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)

Delaware 75-2402409  
(State or Other Jurisdiction of (I.R.S. Employer  
Incorporation or Organization) 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 Website, 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) (Check one):

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

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As of July 27, 2016, the registrant had 550,380,939 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 (“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, 2015, and described from time to time in our other reports filed with the Securities and Exchange Commission. We do not undertake an 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 losses and may not generate sustained positive cash flow sufficient to fund our operations and research and development programs;
- the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments;
- our research and development activities may not result in commercially viable products;
- that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results;
- that the launch of commercial sales for Rayaldee may not be successful;
- that we may fail to obtain regulatory approval for or successfully commercialize our product candidates;
- that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied;
- our ability to develop a pharmaceutical sales and marketing infrastructure;
- our ability and our distribution and marketing partners’ ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates and the operation of our laboratories;
- the performance of our third-party distribution partners, licensees and manufacturers over which we have limited control;
- our success is dependent on the involvement and continued efforts of our Chairman and Chief Executive Officer;
- integration challenges for Bio-Reference, EirGen and other acquired businesses;
- changes in regulation and policies in the United States and other countries, including increasing downward pressure on health care reimbursement;
- our ability to manage our growth and our expanded operations;
- increased competition, including price competition;
- changing relationships with payers, including the various state and multi-state Blues programs, suppliers and strategic partners;
- efforts by third-party payors to reduce utilization and reimbursement for clinical testing services;
- failure to timely or accurately bill for our services;
- failure to obtain and retain new clients and business partners, or a reduction in tests ordered or specimens submitted by existing clients;
- failure to establish, and perform to, appropriate quality standards to assure that the highest level of quality is observed in the performance of our testing services;

failure to maintain the security of patient-related information;  
our ability to obtain and maintain intellectual property protection for our products;  
our ability to defend our intellectual property rights with respect to our products;  
our ability to operate our business without infringing the intellectual property rights of others;  
our ability to attract and retain key scientific and management personnel;  
our need for, and ability to obtain, additional financing;  
• adverse results in material litigation matters or governmental inquiries;  
failure to obtain and maintain regulatory approval outside the U.S.; and  
legal, economic, political, regulatory, currency exchange, and other risks associated with international operations.

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## 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” refer 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)

	June 30, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 156,015	\$ 193,598
Marketable securities	15,634	—
Accounts receivable, net	213,372	193,875
Inventory, net	42,046	39,681
Other current assets and prepaid expenses	78,506	26,904
Total current assets	505,573	454,058
Property, plant and equipment, net	128,274	131,798
Intangible assets, net	804,445	638,152
In-process research and development	606,035	792,275
Goodwill	691,060	743,348
Investments, net	34,249	34,716
Other assets	4,385	4,841
Total assets	\$2,774,021	\$ 2,799,188
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$61,062	\$ 72,535
Accrued expenses	209,848	167,899
Current portion of lines of credit and notes payable	10,327	11,468
Total current liabilities	281,237	251,902
2033 Senior Notes and estimated fair value of embedded derivatives, net of discount	45,233	48,986
Deferred tax liabilities, net	207,595	226,036
Other long-term liabilities, principally deferred revenue and line of credit	224,316	292,470
Total long-term liabilities	477,144	567,492
Total liabilities	758,381	819,394
Equity:		
Common Stock - \$0.01 par value, 750,000,000 shares authorized; 548,301,575 and 546,188,516 shares issued at June 30, 2016 and December 31, 2015, respectively	5,483	5,462
Treasury Stock - 586,760 and 1,120,367 shares at June 30, 2016 and December 31, 2015, respectively	(1,911 )	(3,645 )
Additional paid-in capital	2,736,816	2,705,385
Accumulated other comprehensive loss	(23,431 )	(22,537 )
Accumulated deficit	(701,317 )	(704,871 )
Total shareholders' equity	2,015,640	1,979,794
Total liabilities and equity	\$2,774,021	\$ 2,799,188



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

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OPKO Health, Inc. and Subsidiaries

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

(In thousands, except share and per share data)

	For the three months ended June 30,		For the six months ended June 30,		
	2016	2015	2016	2015	2015
Revenues:					
Revenue from services	\$266,012	\$1,908	\$518,534		\$3,977
Revenue from products	22,807	22,848	42,706		

shares of Common Stock beneficially owned by Frost Group. The 184,325,505 total shares of Common Stock beneficially owned by Gamma Trust constitute 33.0% of the Company's outstanding shares of Common Stock, based upon 559,404,941 shares of Common Stock outstanding as of August 1, 2017. Dr. Frost is the sole trustee of Gamma Trust and holds sole voting and dispositive power with respect to 168,523,394 shares of Common Stock. Gamma Trust has shared voting and dispositive power with respect to the 20,091,062 shares of Common Stock owned by Frost Group.

Frost Nevada directly beneficially owns 395,000 shares of Common Stock. The 395,000 total shares of Common Stock beneficially owned by Frost Nevada constitute 0.1% of the Company's outstanding shares of Common Stock, based upon 559,404,941 shares of Common Stock outstanding as of August 1, 2017. Dr. Frost is the sole trustee of Frost Nevada and holds sole voting and dispositive power with respect to 395,000 shares of Common Stock.

In addition, the Phillip and Patricia Frost Philanthropic Foundation, Inc., which is controlled by Dr. Frost and his wife, owns 2,851,830 shares of Common Stock. Dr. Frost, as the sole trustee of Gamma Trust, which is the controlling member of Frost Group, may be deemed to beneficially own the 20,091,062 shares of Common Stock beneficially owned by Frost Group and the 164,234,443 shares of Common Stock beneficially owned by Gamma Trust. Dr. Frost, as the sole trustee of Frost Nevada may be deemed to beneficially own the 395,000 shares of Common Stock beneficially owned by Frost Nevada. The 191,466,286 shares of Common Stock beneficially owned by Dr. Frost constitute 34.2% of the Company's outstanding shares of Common Stock, based upon 559,404,941 shares of Common Stock outstanding as of August 1, 2017. Dr. Frost, as sole trustee of Gamma Trust, has sole voting and dispositive power over 164,234,443 shares of Common Stock. Dr. Frost, as sole trustee of Frost Nevada, has sole voting and dispositive power over 395,000 shares of Common Stock. Dr. Frost has shared voting and dispositive power with respect to 20,091,062 shares of Common Stock owned by Frost Group and 2,851,830 shares of Common Stock owned by the Phillip and Patricia Frost Philanthropic Foundation, Inc. Dr. Frost individually owns 3,068,951 shares of Common Stock and options to acquire 825,000

shares of Common Stock, which are exercisable within 60 days, and has sole voting and dispositive power over each.

(c) In the last 60 days prior to the filing of this Amendment No. 15, neither the Frost Group nor Dr. Frost has effected any transactions in the shares of Common Stock.

In the last 60 days prior to the filing of this Amendment No. 15, Gamma Trust has acquired a total of 522,100 shares of Common Stock purchased on the open market at prices ranging from \$5.875 to \$6.48 per share. The following table sets forth the information with regard to Common Stock purchased by Gamma Trust on the open market in the last 60 days.

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Date	Quantity	Average Price	Cost	Range
7/24/17	45,000	6.4233	\$289,049.50	6.405-6.44
7/25/17	39,800	6.4113	\$255,170.00	6.395-6.46
7/26/17	36,200	6.3871	\$231,213.78	6.34-6.41
7/27/17	23,600	6.3427	\$149,687.36	6.29-6.42
7/28/17	35,100	6.2966	\$221,012.25	6.25-6.34
8/1/17	46,600	6.2456	\$291,046.41	6.20-6.33
8/2/17	25,000	6.1496	\$153,740.00	6.125-6.17
8/8/17	5,000	6.0500	\$30,250.00	6.05
8/9/17	18,000	6.3460	\$114,227.12	6.06-6.48
8/10/17	39,000	6.2255	\$242,793.94	6.135-6.33
8/11/17	10,000	6.1895	\$61,894.74	6.10-6.235
8/14/17	10,000	6.1527	\$61,526.50	6.135-6.16
8/15/17	25,000	6.0830	\$152,074.32	6.06-6.12
8/16/17	40,000	6.0434	\$241,734.25	6.015-6.07
8/17/17	50,000	5.9610	\$298,047.75	5.875-6.02
8/21/17	25,000	6.1015	\$152,538.50	6.01-6.14
8/22/17	1,800	6.1300	\$11,034.00	6.13
8/23/17	12,000	6.1295	\$73,553.79	6.095-6.16
8/24/17	10,000	6.2353	\$62,352.50	6.14-6.29
8/25/17	25,000	6.1694	\$154,235.91	6.14-6.24

In the last 60 days prior to the filing of this Amendment No. 15, Frost Nevada has acquired a total of 395,000 shares of Common Stock purchased on the open market at prices ranging from \$5.925 to \$6.03 per share. The following table sets forth the information with regard to Common Stock purchased by Frost Nevada on the open market in the last 60 days.

Date	Quantity	Average Price	Cost	Range
9/14/17	260,000	5.9832	\$1,555,623.70	5.925-6.03
9/15/17	80,000	6.0051	\$480,411.00	6.00-6.01
9/18/17	40,000	6.0000	\$240,000.00	5.995-6.01
9/19/17	15,000	6.0066	\$90,099.25	5.9975-6.01

The Reporting Persons undertake to provide upon request by the staff of the Securities and Exchange Commission full information regarding the number of shares purchased or sold at each separate price.

Except as described herein, no other person is known by any Reporting Person to have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, any shares of the Company beneficially owned by them.

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Materials to be Filed as Exhibits.

ITEM 7. Item 7 is amended to add the following text to the end of the item:

Joint Filing Agreement, dated as of September 20, 2017, by and among the Reporting Persons.

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SIGNATURES

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

The Frost Group, LLC

Dated: September 20, 2017 By: /s/ Steven D. Rubin  
Name: Steven D. Rubin  
Title: Vice President

Frost Gamma Investments Trust

Dated: September 20, 2017 By: /s/ Phillip Frost, M.D.  
Name: Phillip Frost, M.D.  
Title: Sole Trustee

Frost Nevada Investments Trust

Dated: September 20, 2017 By: /s/ Phillip Frost, M.D.  
Name: Phillip Frost, M.D.  
Title: Sole Trustee

Dated: September 20, 2017 By: /s/ Phillip Frost, M.D.  
Name: Phillip Frost, M.D.  
Title: Phillip Frost, M.D., Individually