Opko Health, Inc.
Form 10-Q
August 07, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2018.
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 Incorporation or Organization)	(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. ý 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). ý YES ¨ NO
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company"
(in Rule 12b-2 of the Exchange Act) (Check one):

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨
	Emerging growth company ¨

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

As of August 1, 2018, the registrant had 559,770,995 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 (the "Securities Act"). 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, 2017, 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 developing, obtaining regulatory approvals for and commercializing 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 we may fail to obtain regulatory approval for hGH-CTP or successfully commercialize Rayaldee and hGH-CTP;
- that we may not generate profits or cash flow from our laboratory operations or substantial revenue from our pharmaceutical and diagnostic products;
- 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 build a successful 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 Transition Therapeutics, BioReference, EirGen and other acquired businesses;
- changes in regulation and policies in the United States and other countries, including increasing downward pressure on healthcare 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 and collect for our services;
- failure in our information technology systems, including cybersecurity attacks or other data security or privacy incidents;
- 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;

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- failure to obtain and maintain regulatory approval outside the U.S.;
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations; and
- our ability to finance and successfully complete construction of a research, development and manufacturing center in Waterford, Ireland.

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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, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$80,381	$ 91,499
Accounts receivable, net	152,777	165,516
Inventory, net	46,753	49,333
Other current assets and prepaid expenses	41,651	42,513
Total current assets	321,562	348,861
Property, plant and equipment, net	150,156	146,557
Intangible assets, net	648,541	683,835
In-process research and development	645,714	647,347
Goodwill	714,234	717,099
Investments	45,497	40,642
Other assets	5,246	5,615
Total assets	$2,530,950	$ 2,589,956
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$69,061	$ 74,307
Accrued expenses	200,992	230,301
Current portion of 2033 Senior Notes	30,343	—
Current portion of lines of credit and notes payable	6,465	11,926
Total current liabilities	306,861	316,534
2023 Convertible Notes and 2033 Senior Notes	55,894	29,160
Deferred tax liabilities, net	148,255	148,729
Other long-term liabilities, principally contract liabilities, contingent consideration and line of credit	209,444	239,955
Total long-term liabilities	413,593	417,844
Total liabilities	720,454	734,378
Equity:		
Common Stock - $0.01 par value, 750,000,000 shares authorized; 560,169,422 and 560,023,745 shares issued at June 30, 2018 and December 31, 2017, respectively	5,602	5,600
Treasury Stock - 549,907 and 549,907 shares at June 30, 2018 and December 31, 2017, respectively	(1,791)	(1,791)
Additional paid-in capital	2,901,086	2,889,256
Accumulated other comprehensive loss	(13,004)	(528)
Accumulated deficit	(1,081,397)	(1,036,959)
Total shareholders' equity	1,810,496	1,855,578
Total liabilities and equity	$2,530,950	$ 2,589,956

The accompanying unaudited 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,	
	2018	2017	2018	2017
Revenues:				
Revenue from services	$216,055	$233,912	$427,369	$462,456
Revenue from products	28,523	28,966	56,374	51,197
Revenue from transfer of intellectual property and other	19,107	29,723	34,855	45,328