Opko Health, Inc.
Form 10-Q
November 09, 2015
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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 September 30, 2015.
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 (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. 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, 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 x	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 ý NO

As of October 30, 2015, the registrant had 545,011,748 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, 2014, and described from time to time in our other reports filed with the Securities and Exchange Commission. Except as required by law, 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 operating losses and we do not expect to become profitable in the near future.
- We may fail to realize the anticipated benefits of the merger with Bio-Reference Laboratories, Inc. ("Bio-Reference"). The failure to integrate successfully the business and operations of Bio-Reference timely may adversely affect our future results.
- Combining our business with Bio-Reference may be more difficult, costly or time-consuming than expected, which may adversely affect our business results and negatively affect the value of our common stock following the merger.
- Our future results will suffer if we do not effectively manage our expanded operations following the merger with Bio-Reference.
- Third parties may terminate or alter existing contracts or relationships with us or Bio-Reference as a result of the merger.
- We may be unable to retain key Bio-Reference personnel following the merger.
- The market price of our common stock may decline as a result of the merger with Bio-Reference.
- Charges to earnings resulting from the application of the acquisition method of accounting may adversely affect the market value of our common stock following the merger.
- Our technologies are in an early stage of development and are unproven.
- Our business is substantially dependent on our ability to develop, launch and generate revenue from our pharmaceutical and diagnostic programs.
- Our research and development activities, or that of our investees, may not result in commercially viable products.
- Our estimates on the timing and expenditures associated with the build-up of pre-launch inventory and capacity expansion could be over or under actual needs and may adversely affect our operations and financial results.
- 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 United States ("U.S.") Food and Drug Administration ("FDA") or other non-U.S. regulatory authorities.
- We may require substantial additional funding, which may not be available to us on acceptable terms, or at all.
- We may 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.

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- Material weaknesses in the design and operation of the internal control over financial reporting of companies that we acquire could have a material adverse effect on our financial statements.
- The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates.
- Failure to recruit and enroll patients for clinical trials may cause the development of our product candidates to be delayed.
- Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.
- 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.
- The loss of Phillip Frost, M.D., our Chairman and Chief Executive Officer, could have a material adverse effect on our business and product development.
- If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.
- As we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.
- If we fail to acquire and develop other products or product candidates, at all or on commercially reasonable terms, we may be unable to diversify or grow our business.
- We have no experience manufacturing our pharmaceutical product candidates other than at one of our Israel facilities and one of our Irish facilities, and at our Mexican and Spanish facilities, and we have no experience in manufacturing our diagnostic product candidates. We will therefore likely rely on third parties to manufacture and supply our pharmaceutical and diagnostics product candidates, and we would need to meet various standards to satisfy FDA regulations in order to manufacture on our own.
- We currently have no pharmaceutical or diagnostic marketing, sales or distribution capabilities other than in Chile, Mexico, Spain, and Uruguay for sales in those countries and our active pharmaceutical ingredients (“APIs”) business in Israel, and the sales force for our laboratory businesses at OPKO Lab and Bio-Reference. 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 and diagnostic product candidates.
- Certain elements of our business are dependent on the success of ongoing and planned phase 3 clinical trials for Alpharen (Fermagate Tablets), and hGH-CTP.
- 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 exclusive worldwide agreement with Pfizer Inc. (“Pfizer”) is important to our business. If we do not successfully develop hGH-CTP and/or Pfizer does not successfully commercialize hGH-CTP, our business could be adversely affected.
- Our license agreement with TESARO, Inc. (“TESARO”) is important to our business. If TESARO does not successfully commercialize Varubi, 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.
- 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.

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- We license patent rights to certain of our technology from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.
- Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.
- Adverse results in material litigation matters or governmental inquiries could have a material adverse effect upon our business and financial condition.
- If our products have undesirable effects on patients, we could be subject to litigation or product liability claims that could impair our reputation and 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 adversely affect our ability to sell our products or provide our services profitably.
- Failure to obtain and maintain regulatory approval outside the U.S. 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, may not proceed as planned, and may also increase the risk of potential third party claims and litigation.
- We may encounter difficulties in integrating acquired businesses.
- Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.
- Political and economic instability in Europe and Latin America and political, economic, and military instability in Israel or neighboring countries could adversely impact our operations.
- We are subject to fluctuations in currency exchange rates in connection with our international businesses.
- We have a large amount of goodwill and other intangible assets as a result of acquisitions and a significant write-down of goodwill and/or other intangible assets would have a material adverse effect on our reported results of operations and net worth.
- 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.
- The conversion and redemption features of our January 2013 convertible senior notes due in 2033 are classified as embedded derivatives and may continue to result in volatility in our financial statements, including having a material impact on our result of operations and recorded derivative liability.
- Directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that you may 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 New York Stock Exchange (“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.

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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)

	September 30, 2015	December 31, 2014[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$212,144	$ 96,907
Accounts receivable, net	189,725	19,969
Inventory, net	40,693	16,604
Prepaid expenses and other current assets	74,854	9,389
Total current assets	517,416	142,869
Property, plant and equipment, net	126,822	16,411
Intangible assets, net	660,287	62,649
In-process research and development	812,723	793,152
Goodwill	761,234	224,292
Investments, net	34,695	22,453
Other assets, principally deferred tax assets	102,676	5,838
Total assets	$3,015,853	$ 1,267,664
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$77,969	$ 8,744
Accrued expenses	201,113	60,912
Current portion of lines of credit and notes payable	78,508	13,455
Total current liabilities	357,590	83,111
2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	44,206	131,454
Deferred tax liabilities	408,213	167,153
Other long-term liabilities, principally deferred revenue and contingent consideration	236,476	50,205
Total long-term liabilities	688,895	348,812
Total liabilities	1,046,485	431,923
Equity:		
Common Stock - $0.01 par value, 750,000,000 shares authorized; 545,951,707 and 433,421,677 shares issued at September 30, 2015 and December 31, 2014, respectively	5,459	4,334
Treasury Stock - 1,120,367 and 1,245,367 shares at September 30, 2015 and December 31, 2014, respectively	(3,645)	(4,051)
Additional paid-in capital	2,696,420	1,529,096
Accumulated other comprehensive income (loss)	(20,992)	(12,392)
Accumulated deficit	(706,474)	(674,843)
Total shareholders' equity attributable to OPKO	1,970,768	842,144
Noncontrolling interests	(1,400)	(6,403)

Total shareholders' equity	1,969,368	835,741
Total liabilities and equity	$3,015,853	$ 1,267,664

(1) As of December 31, 2014, total assets include $7.6 million and total liabilities include $12.1 million related to SciVac Ltd ("SciVac"). SciVac was a consolidated variable interest entity which we deconsolidated in July 2015. Refer to Note 5. SciVac's consolidated assets were owned by SciVac and SciVac's consolidated liabilities had no recourse against us.

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 September 30,		For the nine months ended September 30,	
	2015	2014	2015	2014
Revenues:				
Revenue from services	$103,919	$2,482	$107,929	$6,606
Revenue from products	20,765	17,291	59,066	58,510
Other revenue, principally transfer of intellectual property	18,350	—	48,552	476
Total revenues	143,034	19,773	215,547	65,592
Costs and expenses:				
Cost of service revenue	56,670	2,359	61,434	7,088
Cost of product revenue	10,658	8,761	30,650	28,987
Selling, general and administrative	55,246	14,010	93,629	42,697
Research and development	18,937	20,517	74,010	57,744
In-process research and development	—	—	—	10,055
Contingent consideration	1,636	19,592	6,471	24,078
Amortization of intangible assets	8,110	2,735	14,011	8,304
Grant repayment (Note 12)	—	—	25,889	—
Total costs and expenses	151,257	67,974	306,094	178,953
Operating income (loss)	(8,223)	(48,201)	(90,547)	(113,361)
Other income and (expense), net:				
Interest income	13	402	27	450
Interest expense	(2,745)	(2,402)	(6,296)	(10,572)
Fair value changes of derivative instruments, net	32,244	3,305	(34,100)	3,758
Other income (expense), net	17,482	(2,764)	16,734	2,044
Other income and (expense), net	46,994	(1,459)	(23,635)	(4,320)
Income (loss) before income taxes and investment losses	38,771	(49,660)	(114,182)	(117,681)
Income tax benefit (provision)	92,978	(294)	87,218	(1,009)
Income (loss) before investment losses	131,749	(49,954)	(26,964)	(118,690)
Loss from investments in investees	(3,502)	(60)	(6,067)	(2,486)
Net income (loss)	128,247	(50,014)	(33,031)	(121,176)
Less: Net loss attributable to noncontrolling interests	—	(1,345)	(1,400)	(2,481)
Net income (loss) attributable to common shareholders	$128,247	$(48,669)	$(31,631)	$(118,695)
Earnings (loss) per share:				
Earnings (loss) per share, basic	$0.26	$(0.11)	$(0.07)	$(0.28)
Earnings (loss) per share, diluted	$0.25	$(0.11)	$(0.07)	$(0.28)
Weighted average common shares outstanding, basic	500,562,254	427,577,102	469,931,486	418,649,421
Weighted average common shares outstanding, diluted	514,320,570	427,577,102	469,931,486	418,649,421

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 COMPREHENSIVE INCOME (LOSS)
(Unaudited)
(In thousands)

	For the three months ended September 30,		For the nine months ended September 30,	
	2015	2014	2015	2014
Net income (loss)	$128,247	$(50,014)	$(33,031)	$(121,176)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss) from equity investments	(1,452)	(3,169)	(5,998)	(4,781)
Available for sale investments:				
Change in unrealized gain (loss), net of tax	(661)			