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 March 31, 2021.

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.01 per share	OPK	NASDAQ Global Select Market

Indicate by check mark whether the registrant: (1) has filed all reports required l

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in Rule 12b-2 of the Exchange Act:ṅ b

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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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange 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, including the potential impact of the COVID-19 pandemic on our businesses, operating results, cash flows and/or financial condition. 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, 2020, and described from time to time in our other filings with the Securities and Exchange Commission (the "SEC"). We do not undertake any obligation to update forward-looking statements, except to the extent required by applicable law. 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:

- our business may be materially adversely affected by the coronavirus (COVID-19) pandemic, including the impact on our sales and operations from continued or increasing infection rates and potential declines in testing needs should infection rates decline;
- we have had a history of losses and may not generate sustained positive cash flow sufficient to fund our operations and research and development programs;
- our need for, and ability to obtain, additional financing when needed on favorable terms, or at all;
- adverse results in material litigation matters or governmental inquiries;
- 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 (Somatrogon) or successfully commercialize hGH-CTP (Somatrogon);
- that we may not generate or sustain profits or cash flow from our laboratory operations or substantial revenue from *Rayaldee* and our other 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 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;
- changes in regulation and policies in the United States ("U.S.") 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 payors, including the various state and multi-state programs, suppliers and strategic partners;
- efforts by third-party payors to reduce utilization and reimbursement for clinical testing services;

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 consolidated subsidiaries.

Item 1. Financial Statements

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

OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share data)

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CONSOLIDATED STATEMENTS OF EQUITY
(Unaudited)
(In thousands, except share data)
For the three months ended March 31, 2020

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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

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adoption of work-from-home or shelter-in-place policies. We also continue to see a substantial need for COVID-19 testing by our existing clients and expect new clients as infections for the virus continue.

In March 2020, in response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law. The CARES Act provides numerous tax provisions and other stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses, temporary changes to the prior and future limitations on interest deductions, temporary suspension of certain payment requirements for the employer portion of Social Security taxes, technical corrections from prior tax legislation for tax depreciation of certain qualified improvement property, and the creation of certain payroll tax credits associated with the retention of employees.

We have received, or expect to receive a number of benefits under the CARES Act including, b

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A total of 74,623,270 and 69,339,603 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the three months ended March 31, 2021, and 2020, respectively, because their inclusion would be antidilutive. A full presentation of diluted earnings per share has not been provided because the required adjustments to the numerator and denominator resulted in diluted earnings per share equivalent to basic earnings per share.

During the three months ended March 31, 2021, 117,500 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 117,500 shares of Common Stock. Of the 117,500 Common Stock options and Common Stock warrants exercised, no shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the three months ended March 31, 2020, no Common Stock options or Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of no shares of Common Stock.

NOTE 7 DEBT

As of March 31, 2021 and December 31, 2020, our debt consists of the following:

(In thousands)	March 31, 2021	December 31, 2020
2025 Notes	$ 158,278	$ 156,163
2023 Convertible Notes	63,453	62,776
2033 Senior Notes	3,050	3,050
JP Morgan Chase	—	7,057
Chilean and Spanish lines of credit	16,093	15,897
Current portion of notes payable	1,724	1,749
Long term portion of notes payable	3,919	4,513
Total	$ 246,517	$ 251,205
Balance sheet captions		
Convertible Notes	$	

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We may no

NOTE 10 DERIVATIVE CONTRACTS

The following table summarizes the fair values and the presentation of our derivative assets (liabilities) in the Condensed Consolidated Balance Sheets:

(In thousands)	Balance Sheet Component	March 31, 2021	December 31, 2020
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 96	$ 74
Forward contracts	Unrealized gains on forward contracts are recorded in Other current assets and prepaid expenses. Unrealized (losses) on forward contracts are recorded in Accrued expenses.	$ 206	$ (1,040)

We enter into foreign currency forward exchange contracts with respect to 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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At March 31, 2021, we were committed to make future purchases for inventory and other items in 2021 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating approximately $301.5 million.

NOTE 13 REVENUE RECOGNITION

We generate revenues from services, products and intellectual property as follows:

Revenue from services

Revenue for laboratory services is recognized at the time test results are reported, which approximates when services are provided and the performance obligations are satisfied. Services are provided to patients covered by various third-party payor programs including various managed care organizations, as well as the Medicare and Medicaid [illegible] for contractual discounts, allowances for differences between the amounts billed and estimated program payment amounts, and implicit price concessions provided to uninsured patients which are all elements of variable consideration.

The following are descriptions of our payors for laboratory services:

Healthcare Insurers. Reimbursements from healthcare insurers are based on negotiated fee-for-service schedules. Revenues consist of amounts billed, net of contractual allowances for differences between amounts billed and the estimated consideration we expect to receive from such payors, which considers historical denial and collection experience and the terms of our contractual arrangements. [illegible]

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with provisions of gross or net revenue presentation. The corresponding revenues or offset to research and development expenses are recognized as the related performance obligations are satisfied.

Sales-based Milestone and Royalty Payments: Our customers may be required to pay us sales-based milestone payments or royalties on future sales of commercial products. We recognize revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the customer's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license to our intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

Other Potential Products and Services: Arrangements may include an option for license rights, future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's election. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations at the inception of the contract and revenue is recognized only if the option is exercised and products or services are subsequently delivered or when the rights expire. If the promise is based on market terms and not considered a material right, the option is accounted for if and when exercised. If we are entitled to additional payments when the licensee exercises these options, any additional payments are generally recorded in license or other revenues when the licensee obtains control of the goods, which is upon delivery.

For the three months ended March 31, 2021 and 2020, revenue from transfer of intellectual property principally reflects $2.8 million and $8.7 million of revenue, respectively, related to the Pfizer Transaction (as defined below). Refer to Note 14 for discussion of the Pfizer Transaction.

Contract liabilities relate to cash consideration that OPKO receives in advance of satisfying the related performance obligations.Changes in the contractual liabilities balance during the three months ended March 31, 2021 are as follows:

(In thousands)		
Balance at December 31, 2020	$	16,378
Balance at March 31, 2021		15,588
Revenue recognized in the period from:		
Amounts included in contracts liability at the beginning of the period		790

The contract liability balance at March 31, 2021 related primarily to accelerated payments received as part of the CARES Act. Refer to Note 2.

NOTE 14 STRATEGIC ALLIANCES

Japan Tobacco Inc.

On October 12, 2017, EirGen, our wholly owned subsidiary, and Japan Tobacco Inc. ("JT") entered into a Development and License Agreement (the "JT Agreement") granting JT the exclusive rights for the development and commercialization of *Rayaldee* in Japan (the "JT Territory"). The license grant to JT covers the therapeutic and preventative use of the product for (i) SHPT in non-dialysis and dialysis patients with CKD, (ii) rickets, and (iii) osteomalacia (the "JT Initial Indications"), as well as such additional indications as may be added to the scope of the license subject to the terms of the JT Agreement (the "JT Additional Indications" and together with the JT Initial Indications, the "JT Field").

In connection with the license, OPKO received an initial upfront payment of $6 million and received another $6 million upon the initiation of OPKO's phase 2 study for *Rayaldee* in dialysis patients in the U.S. in September 2018 (the "Initial Consideration"). OPKO is also eligible to receive up to an additional aggregate amount of $81 million upon the achievement of certain regulatory and development milestones by JT for *Rayaldee* in the JT Territory, and $75 million upon the achievement of certain sales based milestones by JT in the JT Territory. OPKO is also entitled to receive tiered, double digit royalty payments at percentages ranging from low double digits to mid-teens on net sales of *Rayaldee* within the JT Territory. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for *Rayaldee* in Japan and for all commercial activities pertaining to *Rayaldee* in Japan.

The JT Agreement provides for the following: (1) an exclusive license in the JT Territory in the JT Field for the development and commercialization of *Rayaldee*; and (2) at JT's option, EirGen will supply products to support the development, sale and commercialization of the products to JT in the JT Territory.

The Initial Consideration will be recognized over the performance period through 2021, when we anticipate completing the transfer of license materials specified in the JT Agreement and our performance obligation is complete. Payments received

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(in thousands)	Classification on the Balance Sheet	March 31, 2021	December 31, 2020
Assets			
Operating lease assets	Operating lease right-of-use assets	$ 38,631	$ 37,735
Finance lease assets	Property, plant and equipment, net	4,793	5,258
Liabilities			
Current			
Operating lease liabilities	Current maturities of operating leases	10,305	9,028
Accrued expenses	Current maturities of finance leases	2,287	2,453
Long-term			
Operating lease liabilities	Operating lease liabilities	32,394	29,760
Other long-term liabilities	Finance lease liabilities	$ 2,506	$ 2,805
Weighted average remaining lease term			
Operating leases		5.8 years	5.4 years
Finance leases		2.4 years	2.3 years
Weighted average			

NOTE 17 SUBSEQUENT EVENTS

On April 28, 2021, an Order Granting Final Approval of Class Action Settlement and Order of Dismissal with Prejudice was entered in the United States District Court for the Southern District of Florida, Miami Division ("Order"), approving the settlement of the previously disclosed class action lawsuit ("Class Action Suit") involving several individuals, including the Company and its CEO and Chairman, Dr. Phillip Frost, stemming from the allegations in the September 7, 2018 complaint filed by the Securities and Exchange Commission which was subsequently settled, as previously disclosed in the Annual Report. The Order provides for, among other things, the settlement and release of the class action claims against the Company and Dr. Frost, for $16.5 million, a significant portion of which has been covered by our insurance carriers.

We have reviewed all subsequent events and transactions that occurred after the date of our March 31, 2021 Condensed Consolidated Balance Sheet, through the time of filing this Quarterly Report on Form 10-Q.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

OVERVIEW

You should read this discussion together with the unaudited Condensed Consolidated Financial Statements, related notes, and other financial information included elsewhere in this Quarterly Report on Form 10-Q together with our audited consolidated financial statements, related notes, and other information contained in our Annual Report on Form 10-K for the year ended December 31, 2020 (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 I, Item 1A of the Form 10-K and as described from time to time in our other filings with the Securities and Exchange Commission. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories, Inc. ("BioReference"), one of the nation's largest full service laboratories with a core genetic testing business and an almost 300-person sales and marketing team to drive growth and leverage new products, including the *4Kscore* test. Our pharmaceutical business features *Rayaldee*, a U.S. Food and Drug Administration ("FDA") approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency (launched in November 2016) and a pipeline of products in various stages of development. Our leading product in development is hGH-CTP (Somatrogon), a once-weekly human growth hormone for which we have partnered with Pfizer, Inc. ("Pfizer"). Regulatory applications for hGH-CTP (Somatrogon) approval have been submitted in the U.S., Europe and Japan, among other territories. We are incorporated in Delaware, and our principal executive offices are located in leased offices in Miami, Florida.

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The following table summarizes the components of our research and development expenses:

Research and Development Expenses	Three months ended March 31,	
	2021	2020
External expenses:		
Manufacturing expense for biological products	$ 1,567	$ 3,037
Phase III studies	2,351	3,042
Post-marketing studies	5	840
Earlier-stage programs	5,193	3,604
Research and development employee-related expenses	5,328	6,382
Other internal research and development expenses	1,383	1,645
Third-party grants and funding from collaboration agreements	(10)	—

The following table provides information as of March 31, 2021, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands, ratio T							

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PART II. OTHER I

Item 1A. Risk Factors

Except as set forth in this Item 1A, there have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit 10.1

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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: April 28, 2021

OPKO Health, Inc.

/s/ Adam Logal

Adam Logal
Senior Vice President and Chief Financial Officer

Exhibit 32.1

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002, I, Phillip Frost, Chief Executive Officer of OPKO Health, Inc. (the "Company"), hereby certify that:

The Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 28, 2021

/s/ Phillip Frost, M.D.
Phillip Frost, M.D.
Chief Executive Officer