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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, 2021, 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.

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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 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 BALANCE SHEETS
(Unaudited)

OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaud o no

CONSOLIDATED STATEMENTS OF EQUITY
(Unaudited)
(In thousands, except share data)
For the three and nine months ended September 30, 2022

CONSOLIDATED STATEMENTS OF EQUITY
(Unaudited)
(In thousands, except share data)
For the three and nine months ended September 30, 2021

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at June 30, 2021	689,817,971	$ 6,898	(8,655,082)	$ (1,791)	$ 3,214,351	$ (9,932)	$ (1,466,941)	$ 1,742,585
Equity-based compensation expense	—	—	—	—	3,822			

OPKO Health, Inc. and Subsidiaries
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

NOTE 1 BUSINESS AND ORGANIZATION

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 Health, LLC, formerly known as BioReference Laboratories, Inc. ("BioReference"), one of the nation's largest full service laboratories with an 180 person sales and marketing team to drive growth and leverage new products. 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 and a pipeline of products in various stages of development. Our leading product in development is Somatrogon (hGH-CTP), a once-weekly human growth hormone for which we have partnered with Pfizer, Inc. ("Pfizer") and successfully completed a phase 3 study in August 2019. Regulatory applications for Somatrogon (hGH-CTP) have been submitted to the applicable regulatory bodies for review in several countries around the world.

the closing price per share of our Common Stock of $ 2.44 as reported by NASDAQ Global Sel

Impact of COVID-19

We continue to be a part of the coordinated public and private sector response to SARS-CoV-2, a novel strain of coronavirus, referred to as COVID-19. There continues to be a high level of uncertainty relating to how the pandemic will evolve, how governments and consumers will react, and whether the pandemic will ĊΦVID

liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from these estimates.

Cash and cash equivalents. Cash and cash equivalents include 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, certificates of deposit and U.S. treasury securities.

Inventories. Inventories are valued at the lower of cost and net realizable value. Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost and net realizable value. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which are used in our testing laboratories. Inventory obsolescence expense for the three and nine months ended September 30, 2022 was $3.0 million and $4.0 million, respectively. Inventory obsolescence expense for the three and nine months ended September 30, 2021 was $1.3 million and $5.3 million, respectively.

Goodwill and intangible assets. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired in business combinations accounted for by the acquisition method of accounting. Refer to Note 5 for additional information. Goodwill, in-process research and development ("IPR&D") and other intangible assets acquired in business combinations, licensing and other transactions was $1.6 billion and $1.4 billion, respectively, at September 30, 2022 and December 31, 2021.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. [illegible] the purchase price over the

existing assets and liabilities and the respective tax bases and for operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment. Valuation allowances on certain U.S. deferred tax assets and non-U.S. deferred tax assets are established, because realization of these tax benefits through future taxable income does not meet the more-likely-than-not threshold.

We operate in various countries and tax jurisdictions globally. For interim reporting purposes, we record income taxes based on the expected effective income tax rate, taking into consideration year to date and global forecasted tax results. For the nine months ended September 30, 2022, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the valuation allowance against certain U.S. and non-U.S. deferred tax assets, the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Revenue recognition. We recognize revenue when a customer obtains control of promised goods or services in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* ("Topic 606"). The amount of revenue that is recorded reflects the consideration that we expect to receive in exchange for those goods or services. We apply the following five-step model in order to determine this amount: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation.

We apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Fgat as

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Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of September 30, 2022 and December 31, 2021:

(in thousands)	As of September 30, 2022	

that most significantly impact the econao

We may not redeem the 2025 Notes prior to February 15, 2022. We may redeem for cash any or all of the 2025 Notes, at our option, on or after February 15, 2022, if the last reported sale price of our Common Stock has been at least 130% of the then current conversion price for the notes for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2025 Notes.

If we undergo a fundamental change, as defined in the indenture governing the 2025 Notes, prior to the maturity date of the 2025 Notes, holders may require us to repurchase for cash all or any portion of their notes at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The 2025 Notes are our senior unsecured obligations and rank senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the 2025 Notes; equal in right of payment to any of our existing and future liabilities that are not so subordinated; effectively junior in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally junior to all indebtedness and other liabilities (including trade payables) of our current or future subsidiaries.

In May 2021, we entered into exchange agreements with certain holders of the 2025 Notes, pursuant to which the holders exchanged $ 55.4 million in aggregate principal amount of the outstanding 2025 Notes for 19,051,270 shares of our Common Stock (the “Exchange”). We recorded an $ 11.1 million non-cash loss related to the Exchange during the second quarter of 2021.

In conjunction with the issuance of the 2025 Notes, we agreed to loan up to 30,000,000 shares of our Common Stock to affiliates of the underwriter in order to assist investors in the 2025 Notes to hedge their position. Following consummation of the Exchange, the number of outstanding borrowed shares of Common Stock was reduced by approximately 8,105,175 shares. As of September 30, 2022 and December 31, 2021, a total of 21,144,825 and 21,144,825 shares remained outstanding under the share lending arrangement, respectively. We will not receive any of the proceeds from the sale of the borrowed shares, but we received a one-time nominal fee of $0.3 million for the newly issued shares. Shares of our Common Stock outstanding under the share lending arrangement are excluded from our outstanding common stock

fees and charges, including an unused commitment fee of 0.375% if the average quarterly availability is 50% or more of the revolving commitment, or 0.25% if the average quarterly availability is less than or equal to 50% of the revolving commitments.

As of September 30, 2022 and December 31, 2021, $ 7.4 million and no amount, respectively, was outstanding under the Credit Agreement.

The Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require BioReference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws and restrictions on the ability of BioReference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the Credit Agreement, notwithstanding the ability of BioReference to meet its debt service obligations. The Credit Agreement also includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Credit Agreement and execution upon the collateral securing the obligations under the Credit Agreement. Substantially all the assets of BioReference and its subsidiaries are restricted from sale, tran , ga gat

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

programs, and disclosure programs; (ii) provide management certifications and compliance training and education; (iii) establish written compliance policies and procedures to meet federal health care program requirements; (iv) create procedures designed to ensure compliance with the Anti-Kickback Statute and/or Stark Law; (v) engage an independent review organization to conduct a thorough review of BioReference' s systems, policies, processes and procedures related to certain arrangements; (vi) implement a risk assessment and internal review process; (vii) establish a disclosure program for whistleblowers; and (viii) report or disclose certain events and physician payments. The Company's or BioReference's failure to comply with its obligations under the CIA could result in monetary penalties and the exclusion from participation in Federal Health Care Programs. The CIA does not apply to any of the Company's subsidiaries other than BioReference, and its scope is generally limited to "focus arrangements", which are those "arrangements" (as defined in the CIA) (i) between BioReference and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value, or (ii) is between BioReference and any physician (or a physician's immediate family member). Most of these measures have already been implemented at BioReference. Following its acquisition of BioReference, the Company and BioReference implemented robust compliance measures that substantially align with those actions required under the CIA.

GeneDx, Inc., the Company's former subsidiary, received a letter dated May 26, 2022 from the Texas Medicaid Office of the Inspector General stating that certain testing provided by GeneDx was not eligible for reimbursement by the Texas Medicaid program, because the testing was considered non-covered by the Texas Medicaid program at the time the tests were performed and/or GeneDx did not hold the requisite CLIA subspecialty classifications for the testing. The Company is working with Sema4 to investigate these issues. Following recent communication, it appears the CLIA subspecialty classification issue has been addressed to the satisfaction of the Texas Medicaid Office of the Inspector General. The potential non-covered testing issue, however, remains under investigation. The Texas Medicaid Office has expressed in writing a potential repayment liability of approximately $784 thousand. At this time, the Company can express no opinion as to the likelihood of an unfavorable outcome or the range of potential loss in this matter.

On March 1, 2019, the Company received a Civil Investigative Demand ("CID") from the U.S. Department of Justice ("DOJ"), Washington, DC. The CID sets forth document requests and interrogatories in connection with allegations that the Company and certain of its affiliates violated the False Claims Act and/or the Anti-Kickback Statute. On January 13, 2022, the Federal Government notified the U.S.D.C., Middle District Florida, Jacksonville Division, that it is declining to intervene in the matter but retains the right, via the Attorney General, to consent to any proposed dismissal of the action by the Court. On February 9, 2022, the States of Florida, Georgia, and Commonwealth of Massachusetts notified the U.S.D.C., Middle District Florida, Jacksonville Division, that they are declining to intervene in the matter. Notwithstanding the above declinations, on February 17, 2022, the Company was served with the Relator's Summons and Complaint ("Complaint"), which had been previously sealed. The complaint alleges violations of the False Claims Act, the California Fraud Preventions Act, the Florida False Claims Act, the Massachusetts False Claims Act, the Georgia False Medicaid Claims Act, and illegal kickbacks. The Company is reviewing and assessing the allegations made in the Complaint and, at this point, has not determined whether there is any merit to these claims nor can it determine the extent of any potential liability. While management cannot predict the outcome of these matters at this time, the ultimate outcome could be material to our business, financial condition, results of operations, and cash flows.

On November 26, 2019, BioReference received a CID from the DOJ. The CID stated that the DOJ was investigating whether BioReference paid unlawful remuneration to health care practitioners in violation of the Anti-Kickback Statute or Stark law and thus submitted or caused to be submitted false claims to government health care programs in violation of the False Claims Act. The time period covered by the DOJ's requests was January 1, 2011 through November 26, 2019. BioReference has fully cooperated with the DOJ by submitting the requested information and making current employees available for interviews, and the DOJ made a presentation to BioReference regarding its position. The parties have reached an agreement on the settlement amount, which is approximately $10 million, excluding attorney fees. As of December 31, 2021, $ 10.0 million was recorded in Accrued expenses, respectively, which the Company paid in full during during the third quarter of 2022.

On April 8, 2019, MabVax Therapeutics Holdings, Inc. filed a lawsuit in the Superior Court of California, County of San Diego against a number of individuals and entities, including the Company, Dr. Frost, Steven Rubin, the Company's Executive Vice President-Administration, and an entity affiliated with Dr. Frost, based on the allegations raised in the SEC Complaint. The lawsuit seeks an award for actual and punitive damages, pre- and post-judgment interest; that the defendants be required to make full disclosure and accounting of their interests and transactions in plaintiff's securities; costs of the suit, and reasonable attorney's fees; and such other legal and equitable relief as the Court may deem proper under the circumstances. On January 31, 2022, plaintiffs entered into a confidential mutual release and settlement agreement with the Company, Dr. Frost, Frost Gamma Investment Trust, and Steve Rubin, which has been approved by the United States Bankruptcy Court for the District of Delaware.

(In thousands)	Three months ended September 30, 2022		Nine months ended September 30,	

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2021	$ 2,014	$ 5,499	$ 2,639	$ 10,152
Provision related to current period sales	9,816	14,469	846	25,131
Credits or payments made	(9,862)	(12,582)	(1,998)	(24,442)
Balance at September 30, 2022	$ 1,968	$ 7,386	$ 1,487	$ 10,841

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In connection with the VFMCRP Agreement, the parties entered into a letter agreement pursuant to which EirGen granted to VFMCRP an exclusive option (the “Option”) to acquire an exclusive license under certain EirGen patents and technology to use, import, offer for sale, sell, distribute and commercialize the Product in the U.S. solely for the treatment of SHPT in dialysis patients with CKD and vitamin D insufficiency (the “Dialysis Indication”). Upon exercise of the Option, VFMCRP will reimburse EirGen for all of the development costs incurred by EirGen with respect to the Product for the Dialysis Indication in the U.S. VFMCRP would also pay EirGen up to an additional aggregate amount of $555 million of sales-based milestones upon the achievement of certain milestones and would be obligated to pay royalties at percentage rates that range from the mid-teens to the mid-twenties on sales of the Product in the U.S. for the Dialysis Indication. To date, VFMCRP has not exercised its option.

Payments received for regulatory milestones and sales milestones are non-refundable. The regulatory milestones are payable if and when VFMCRP obtains approval from certain regulatory authorities and will be recognized as revenue in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. We account for the sales milestones as royalties and sales milestones payments will be recognized as revenue in the period in which the associated milestone is achieved or sales occur, assuming all other revenue recognition criteria are met.

Pfizer Inc.

In December 2014, we entered into an exclusive worldwide agreement (the “Pfizer Agreement”) with Pfizer for the development and commercialization of our long-acpive w

milestones range from $20.0 million to $90.0 million each and are based on achievement of regulatory approval in the U.S. and regulatory approval and price approval in other major markets. The milestone payments will be recognized as revenue in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. To date, $85.0 million of revenue has been recognized related to the achievement of the milestones.

Other

We have completed strategic deals with numerous institutions and commercial partners. In connection with these agreements, upon the achievement of certacr

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related services are rendered. For the three months ended September 30, 2022, negative revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $5.6 million were recognized. Revenue adjustments for the three months ended September 30, 2022 were primarily due to lower COVID-19 test reimbursement estimates. For the three months ended September 30, 2021, positive revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $0.4 million were recognized. Revenue adjustments for the three months ended September 30, 2022 were primarily due to an increase improvement in COVID-19 test reimbursement estimates.

The composition of revenue from services by payor for the three months ended September 30, 2022 and 2021 was as follows:

	Three mont1p	

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

Research and Development Expenses	Three months ended September 30,	
	2022	2021
External expenses:		
Manufacturing expense for biological products	$ 4,943	$ 1,305
Phase III studies	2,350	2,126
Post-marketing studies	18	27
Earlier-stage programs	3,296	3,160
Research and development employee-related expenses	7,176	5,084
Other internal research and development expenses	798	631
Third-party grants and funding from collaboration agreements	(972)	567
Total research and development expenses	$ 17,609	$ 12,900

The increase in research and development expenses for the three months ended September 30, 2022 was primarily due to higher employee related-expenses as a result of our ModeX acquisition and its related development programs and higher costs on Somatrogon (hGH-CTP). Ongoing expenses on the Somatrogon (hGH-CTP) program support open label extension studies that will continue until market launch of Somatrogon (hGH-CTP) in certain countries, as well as the preparation of applications for marketing approvals. Research and development expenses for the pharmaceutical segment for the three months ended September 30, 2022 and 2021 included equity-based compensation expenses of $869 thousand and $326 thousand, respectively.

Contingent consideration. Contingent consideration for the three months ended September 30, 2022 and 2021 was $0.8 million and $0.5 million reversal of expense, respectively. Contingent consideration for the three months ended September 30, 2022 and 2021 was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal, and potential amounts payable to former stockholders of OPKO Renal in connection therewith, pursuant to our acquisition agreement in March 2013.

Amortization of intangible assets. Amortization of intangible assets was $16.5 million and $4.9 million, respectively, for the three months ended September 30, 2022 and 2021. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. During the first quarter of 2022, we reclassified $590.2 million of IPR&D related to Somatrogon (hGH-CTP) from IPR&D in our Condensed Consolidated Balance Sheet upon the approval of NGENLA (Somatrogon) in Europe and Japan. The assets will be amortized on a straight-line basis over their estimated useful life of approximately 12 years.

Gain on sale of assets. Gain on sale of assets for the three months ended September 30, 2021 was $31.5 million, which is related to an agreement between EirGen, our wholly owned subsidiary, and Horizon Therapeutics plc, to sell one of EirGen's facilities in Waterford, Ireland for $65 million in cash less certain assumed and accrued liabilities relating to transferred employees. The facility housed EirGen's sterile-fill-finish business and was no longer a core component of our ongoing operations and business strategy.

Corporate

Other

Interest income. Interest income for the three months ended September 30, 2022 and 2021 was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

Interest expense. Interest expense for the three months ended September 30, 2022 and 2021 was $3.0 million and $4.3 million, respectively. Interest expense was principally related to interest incurred on the 2025 Notes, the 2023 Convertible Notes, the 2033 Senior Notes, and BioReference's outstanding debt under the A&R Credit Agreement. The decrease in interest expense was primarily due to the impact of the adoption of ASU 2020-06 on the 2025 Notes. Due to the adoption of ASU 2020-06, interest expense decreased due to the elimination of the discount created by recognizing a component of convertible debt in equity. Refer to Note 7.

Fair value changes of derivative instruments, net . Fair value changes of derivative instruments, net for the three months ended September 30, 2022 and 2021, was $0.4 million and $1.3 million reversal of expense, respectively. Derivative reversal of expense for the three months ended September 30, 2022 and 2021 was principally related to the change in fair value on foreign currency forward exchange contracts at OPKO Chile.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2022 and 2021 was $36.7 million and $3.4 million of expense, respectively. Other income (expense), net for the three months ended September 30, 2022, includes $30.6 million of expense due to the decrease in the fair value of our Sema4 investment and we recorded $5.8 million of foreign exchange transaction losses driven by a historically strong dollar. Other expense for the three months ended September 30, 2021 primarily consisted of net unrealized losses recognized during the period on our investments in our equity securities.

Income tax benefit (provision) . Our income tax benefit (provision) for the three months ended September 30, 2022 and 2021 was $40.3 million and $(2.7) million, respectively, and reflects quarterly results using our expected effective tax rate. For the three months ended September 30, 2022, the tax rate differed from the U.S. federal statutory rate of 21% primarily due the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in certain early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report net losses. Loss from investments in investees was $43 thousand and $53 thousand for the three months ended September 30, 2022 and 2021, respectively.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2022 AND 2021

Our consolidated income (loss) from operations for the nine months ended September 30, 2022 and 2021 is as follows:

Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as considerations unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when estimating variable consideration in the recognition of revenue in the period the related services are rendered. For the nine months ended September 30, 2022, negative revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $27.8 million were recognized. Revenue adjustments for the nine months ended September 30, 2022 were primarily due to lower COVID-19 test reimbursement estimates. For the nine months ended September 30, 2021, positive revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $36.0 million were recognized. Revenue adjustments for the nine months ended September 30, 2021 were primarily due to an increase in COVID-19 test reimbursement estimates.

The composition of Revenue from services by payor for the nine months ended September 30, 2022 and 2021 was as follows:

include employee-related expenses such as salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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

Research and Development Expenses	Nine months ended September 30,	
	2022	

Corporate

(In thousands)	For the nine months ended September 30,		

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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 – We operate globally and, as such, we are subject to foreign exchange risk in our commercial operations as portions of our revenues are exposed to changes in foreign currency exchange rates, primarily the Chilean Peso, the Mexican Peso, and the Euro.

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 may be hedged with foreign exchange forward contracts. As foreign exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses on the contracts.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial

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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, 2021.

If OPKO's subsidiary, BioReference, fails to comply with the terms of its Corporate Integrity Agreement ("CIA"), it could be subjected to monetary penalties or the exclusion from participation in the Medicare Program, the Medicaid Program and the TRICARE Program ("Federal Health Care Programs").

The Company and BioReference entered into a five-year CIA with the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS"), effective as of July 14, 2022, concurrent with the execution of a settlement agreement with the United States, acting through the United States Department of Justice and on behalf of the OIG-HHS. The CIA imposes certain compliance, auditing (including by an independent review organization), self-reporting and training requirements with which BioReference must comply. If the Company fails to comply with the terms of the CIA, it could be subject to monetary penalties and/or exclusion from participation in Federal Health Care Programs. Any such suspension, exclusion or termination could result in the revocation or termination of contracts and/or licenses and potentially have a material adverse effect on the results of BioReference's operations. The imposition of monetary penalties and/or termination of contracts with respect to BioReference could adversely affect the Company's profitability and financial condition. The CIA does not apply to any of the Company's subsidiaries other than BioReference, and its scope is generally limited to "focus arrangements", which are those "arrangements" (as defined in the CIA) (i) between BioReference and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value, or (ii) is between BioReference and any physician (or a physician's immediate family member). Most of the compliance, auditing (including by an independent review organization), self-reporting and training requirements have already been implemented at BioReference.

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	Settlement Agreement, dated July 14, 2022, by and among OPKO Health, Inc., BioReference Health, LLC, the United States of America, acting through the United States Depa

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has du

Exhibit 31.1

CERTIFICATIONS

I, Phillip Frost, certify that:

Exhibit 32.1

Certification Pursuant to Section

Exhibit 32.2

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, Adam Logal, Chief Financial Officer of OPKO Health, Inc. (the "Company"), hereby certify that:

The Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 (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: November 8, 2022

/s/ Adam Logal
Adam Logal
Senior Vice President and Chief Financial Officer