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 qh

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

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 (a ☒

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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 a®ments e Aces am

- integration challenges for acquired business;
- 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;
- our ability to maintain reimbursement coverage for our products and services, including *Rayaldee* and the

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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share data)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash anr	̈Ω	

CONSOLIDATED STATEMENTS OF EQUITY
(Unaudited)
(In thousands, except share data)
For the three months ended March 31, 2023 and 2022

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2022	781,306,164	$ 7,813	(8,655,082)	$ (1,791)	$ 3,421,872	$ (43,323)	$ (1,822,923)	$ 1,561,648
Equity-based compensation expense	—	—	—	—	2,717	—	—	2,717
Net loss	—	—	—	—	—	—	(18,267)	(18,267)
Other comprehensive income	—	—	—	—	—	5,712	—	5,712
Balance at March 31, 2023	781,306,164	$ 7,813	(8,655,082)	$ (1,791)	$ 3,424,589	$ (37,611)	$ (1,841,190)	$ 1,551,810

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2021	690,082,283	$ 6,901	(8,655,082)	$ (1,791)	$ 3,222,487	$ (30,492	3	

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 ("BioReference"), one of the nation's largest full service laboratories with a 180-person sales and marketing team to drive growth and leverage new products, and we offer our 4Kscore prostate cancer test through BioReference. 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 Somatrogon (hGH-CTP), a once-weekly human growth hormone injection for which we completed a successful phase 3 study in August 2019 and partnered with Pfizer Inc. ("Pfizer") with respect to Somatrogon (hGH-CTP)'s further development. Regulatory applications for Somatrogon (hGH-CTP) have been submitted to the applicable regulatory bodies for review in several countries around the world. In February 2022, the European Commission granted marketing authorization in the European Union for Somatrogon (hGH-CTP) under the brand name NGENLA® to treat children and adolescents from as young as three years of age with growth disturbance due to insufficient secretion of growth hormone and has been granted pricing approval in Germany. NGENLA® has also been approved in Japan, Canada, and Australia. We also submitted the initial Biologics License Application ("BLA") with the FDA for approval of Somatrogon (hGH-CTP) in the United States and Pfizer received a complete response letter in January 2022. Pfizer and OPKO have evaluated the FDA's comments and are working with the agency to address their inquiries. In May 2022, we acquired ModeX Therapeutics, Inc. ("ModeX"), a biotechnology company focused on developing innovative multi-specific immune therapies for cancer and infectious diseases candidates. ModeX has a robust early-stage pipeline with assets in key areas of immuno-oncology and infectious diseases, and we intend to further expand our pharmaceutical product pipeline through ModeX's portfolio of development candidates.

Through BioReference, we provide laboratory testing services, primarily to customers in the larger metropolitan areas in New York, New Jersey, Florida, Texas, Maryland, California, Pennsylvania, Delaware, Washington, DC, Illinois and Massachusetts, as well as to customers in a number of other states. We offer a comprehensive test menu of clinical diagnostics for blood, urine and tissue analysis. This includes hematology, clinical chemistry, immunoassay, infectious disease, serology, hormones, and toxicology assays, as well as Pap smear, anatomic pathology (biopsies) and other types of tissue analysis, as well as testing for COVID-19. We market our laboratory testing services directly to physicians, geneticists, hospitals, clinics, correctional and other health facilities.

We operate established pharmaceutical platforms in Spain, Ireland, Chile, and Mexico, which are generating revenue and from which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. We have a development and commercial supply pharmaceutical company as well as a global supply chain operation. We also own a specialty active pharmaceutical ingredients ("APIs") manufacturer in Israel, which we expect will facilitate the development of our pipeline of molecules and compounds for our proprietary molecular diagnostic and therapeutic products.

Our research and development activities are primarily performed at facilities in Waterford, Ireland, Kiryat Gat, Israel, and Barcelona, Spain.

On May 9, 2022 (the "Closing Date"), the Company entered into an Agreement and Plan of Merger (the "ModeX Merger Agreement"), in accordance with which we acquired ModeX pursuant to a merger in which ModeX survived as a wholly owned subsidiary of the Company. The Company paid the entirety of the $300.0 million purchase price pursuant to the issuance of an aggregate of 89,907,310 shares (the "Consideration Shares") of the Company's common stock, par value $0.01 per share ("Common Stock"), to the former stockholders of ModeX (the "Selling Stockholders"), of which 10% of such shares were deposited in a twelve-month escrow for purposes of satisfying the potential indemnity obligations of the Selling Stockholders under the ModeX Merger Agreement. Additionally, the Company issued equity awards to ModeX employees in an amount equal to $12.4 million, which was deducted from the consideration payable on the Closing Date. If any of such awards are forfeited or otherwise remain unvested on the four-year anniversary of the Closing Date, Common Stock equal to $2.6 million (valued at the same price used for determining the number of Consideration Shares issuable upon consummation of the ModeX Merger) may be distributed pro rata to ModeX's former stockholders in respect of such forfeited or unvested awards. Shares of Common Stock with respect to such potential distribution have been escrowed and will remain escrowed for such four-year period. For accounting purposes, the shares were valued at $221.7 million, based on the closing price per share of our Common Stock of $2.44 as reported by NASDAQ Global Select Market ("NASDAQ") on the Closing Date. Included in the total fair value of consideration transferred of $221.7 million were $2.3 million of fully vested equity awards.

On January 14, 2022, the Company entered into an Agreement and Plan of Merger and Reorganization (the "GeneDx Merger Agreement") with GeneDx Holdings Corp. (f/k/a "Sema Holdings Corp."), a Delaware corporation ("GeneDx Holdings"), pursuant to which GeneDx Holdings acquired the Company's former subsidiary, GeneDx LLC, (f/k/a GeneDx, Inc. "GeneDx"), in a transaction (the "GeneDx Transaction") that closed on April 29, 2022 (the "GeneDx Closing").

Upon the GeneDx Closing, GeneDx Holdings paid to the Company aggregate consideration of $150 million in cash (before deduction of transaction expenses and other customary purchase price adjustments), together with 80.0 million shares (the "Closing Shares") of GeneDx Holdings' Class A common stock, par value $0.0001 per share ("GeneDx Holdings Common Stock"). Based on the closing stock price of GeneDx Holdings as of April 29, 2022, the total upfront consideration represented approximately $322 million. Additionally, subject to GeneDx achieving certain revenue targets for the fiscal years ending December 31, 2022 and 2023, we are eligible to receive an earnout payment ("Milestone Consideration") in cash or stock (at GeneDx Holdings' discretion) equal to a maximum of 30.9 million shares of GeneDx Holdings' Common Stock if paid in stock. We received 23.1 million shares of Class A Common Stock as a result of GeneDx satisfactorily achieving targets as of December 31, 2022.

In connection with the transactions contemplated by the GeneDx Merger Agreement, on January 14, 2022, the Company entered into a Shareholder Agreement (the "GeneDx Holdings Shareholder Agreement") with an (the

Foreign currency translation. The financial statements of certain of our foreign operations are measured using the local currency as the functional currency. The local currency assets and liabilities are generally translated at the rate of exchange to the U.S. dollar on the balance sheet date. The local currency revenues and expenses are translated at average rates of exchange to the U.S. dollar during the reporting periods. Foreign currency transaction gains (losses) have been reflected as a component of Other income (expense), net within the Condensed Consolidated Statement of Operations and foreign currency translation gains (losses) have been included as a component of the Condensed Consolidated Statement of Comprehensive Income (Loss). During the three months ended March 31, 2023, and 2022, we recorded $1.0 million and $1.1 million, respectively, of transaction gains.

Variable interest entities. The consolidation of a variable interest entity ("VIE") is required when an enterprise has a controlling financial interest. A controlling financial interest in a VIE will have both of the following characteristics: (a) the power to direct the activities of a VIE that most significantly impact the VIE's economic performance and (b) the obligation to absorb losses of the VIE that could potentially be significant to the VIE. Refer to Note 6.

Investments.

During the three months ended March 31, 2023, no options were exercised and no restricted stock units vested, resulting in the issuance of no shares of Common Stock.

During the three months ended March 31, 2022, an aggregate of 55,750 options to purchase shares of our Common Stock were exercised, resulting in the issuance of 55,750 shares of Common Stock. Of the 55,750 options exercised, no shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of such instruments.

NOTE 5 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

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the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No s

(In thousa

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. A motion to dismiss the Complaint was filed on April 25, 2022 and the case was dismissed in March 2023. However, the Relator filed an amended complaint in April 2023. 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.

From time to time, we may receive inquiries, document requests, CIDs or subpoenas from the Department of Justice, OCR, CMS, various payors and fiscal intermediaries, and other state and federal regulators regarding investigations, audits and reviews. In addition to the matters discussed in this note, we are currently responding to CIDs, subpoenas, payor audits, and document requests for various matters relating to our laboratory operations. Some pending or threatened proceedings against us may involve potentially substantial amounts as well as the possibility of civil, criminal, or administrative fines, penalties, or other sanctions, which could be material. Settlements of suits involving the types of issues that we routinely confront may require monetary payments as well as corporate integrity agreements. Additionally, qui tam or "whistleblower" actions initiated under the civil False Claims Act may be pending but placed under seal by the court to comply with the False Claims Act's requirements for filing such suits. Also, from time to time, we may detect issues of non-compliance with federal healthcare laws pertaining to claims submission and reimbursement practices and/or financial relationships with physicians, among other things. We may avail ourselves of various mechanisms to address these issues, including participation in voluntary disclosure protocols. Participating in voluntary disclosure protocols can have the potential for significant settlement obligations or even enforcement actions, but the Company generally has cooperated, and intends to continue to cooperate, with appropriate regulatory authorities as and when investigations, audits and inquiries arise.

of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the third-party payors, are recorded upon settlement.

Government Payors. Reimbursements from government payors are based on fee-for-service schedules set by governmental authorities, including traditional Medicare and Medicaid. 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. Adjustments to the allowances, based on actual receipts from the government payors, are recorded upon settlement.

Client Payors. Client payors include physicians, hospitals, employers, and other institutions for which services are performed on a wholesale basis, and are billed and recognized as revenue based on negotiated fee schedules. Client payors also include cities, states and companies for which BioReference provides COVID-19 testing services.

Patients. Uninsured patients are billed based on established patient fee schedules or fees negotiated with physicians on behalf of their patients. Insured patients (including amounts for coinsurance and deductible responsibilities) are billed based on fees negotiated with healthcare insurers. Collection of billings from patients is subject to credit risk and ability of the patients to pay. Revenues consist of amounts billed net of discounts provided to uninsured patients in accordance with our policies and implicit price concessions. Implicit price concessions represent differences between amounts billed and the estimated consideration that we expect to receive from patients, which considers historical collection experience and other factors including current market conditions. Adjustments to the estimated allowances, based on actual receipts from the patients, are recorded upon settlement.

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as considerations unique to Medicare and Medicaid programs, require us to estimate the potential for retroactive adjustments as an element of variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known. Negative revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods were recognized of $4.8 million and $3.2 million, respectively, for the three months ended March 31, 2023, and 2022. Revenue adjustments for the three months ended March 31, 2023were mainly due to the composition of patient pay mix and, in 2022, mainly to lower reimbursement estimates for COVID-19 testing.

Third-party payors, including government programs, may decide to deny payment or recoup payments for testing they contend were improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. Our revenues may be subject to retroactive adjustment as a result of these factors among others, including without limitation, differing interpretations of billing and coding guidance and changes by government agencies and payors in interpretations, requirements, and “conditions of participation” in various programs. We have processed requests for recoupment from third-party payors in the ordinary course of our business, and it is likely that

(In thousands)	Three months ended March 31, 2023	2022
Healthcare insurers	$ 80,602	$ 95,779
Government payers	20,417	27,588
Client payers	27,168	159,040
Patients	4,181	4,192
Total	$ 132,368	$ 286,599

Revenue from products

We recognize revenue from product sales when a customer obtains control of promised goods or services. The amount of revenue that is recorded reflects the consideration that we expect to receive in exchange for those goods or services. Our estimates for sales returns and allowances are based upon the historical patterns of product returns and allowances taken, matched against the sales from which they originated, and our evaluation of specific factors that may increase or decrease the risk of product returns. Product revenues are recorded net of estimated rebates, chargebacks, discounts, co-pay assistance and other deductions (collectively, "Sales Deductions") as well as estimated product returns which are all elements of variable consideration. Allowances are recorded as a reduction of revenue at the time product revenues are recognized. The actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect Revenue from products in the period such variances become known.

Rayaldee is distributed in the U.S. principally through the retail pharmacy channel, which initiates with the largest wholesalers in the U.S. (collectively, "*Rayaldee* Customers"). In addition to distribution agreements with *Rayaldee* Customers, we have entered into arrangements with many healthcare providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of *Rayaldee.*

We recognize revenue for shipments of *Rayaldee* at the time of delivery to customers after estimating Sales Deductions and product returns as elements of variable consideration utilizing historical information and market research projections. For the three months ended March 31, 2023 and 2022, we recognized $6.6 million and $5.1 million, respectively, in net product revenue from sales of *Rayaldee.*

The following table presents an analysis of product sales allowances and accruals for the three months ended March 31, 2023 and 2022:

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research and development funding would result in revenues or an offset to research and development expenses in accordance 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, 2023 and 2022, we recorded $64.8 million and $6.0 million of revenue from the transfer of intellectual property and other, respectively. For the three months ended March 31, 2023, revenue from transfer of intellectual property and other principally reflects an upfront payment of $50.0 million from Merck and a $7.0 million payment from Vifor (as defined below) triggered by the German price approval for *Rayaldee.* Furthermore, we recorded a $2.5 million payment from Nicoya due to Nicoya's submission of the investigational new drug application to China's Center for Drug Evaluation ("CDE"). For the three months ended March 31, 2023 and 2022, revenue from transfer of intellectual property and other reflects $1.8 million and $2.2 million, respectively, of revenue related to the Pfizer Transaction (as defined below). For the three months ended March 31, 2022, revenue from transfer of intellectual property and other included $3.0 million related to a sales milestone from Vifor.

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, 2023 were as follows:

(In thousands)		
Balance at December 31, 2022	$	138
Balance at March 31, 2023		140
Revenue recognized in the period from:		
Amounts included in contracts liability at the beginning of the period		(2)

NOTE 14 STRATEG anC X r

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development costs that Vifor considers necessary to develop the Product for the use of the Product for the Vifor Initial Indication in the Vifor Territory in the Vifor Field except as otherwise provided in the Vifor Agreement. The first of the clinical studies provided for in the development activities commenced in September 2018.

In connection with the Vifor Agreement, the parties entered into a letter agreement pursuant to which EirGen granted to Vifor 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, Vifor has agreed to reimburse EirGen for all of the development costs incurred by EirGen with respect to the Product for the Dialysis Indication in the U.S. Vifor 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, Vifor has not exercised the Option.

Payments received for regulatory milestones and sales milestones are non-refundable. The regulatory milestones are payable if and when Vifor 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-acting Somatrogon (hGH-CTP) for the treatment of growth hormone deficiency ("GHD") in adults and children, as well as for the treatment of growth failure in children born small for

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were completed. As of March 31, 2023 and December 31, 2022, we had no contract liabilities related to the Pfizer Transaction.

The Pfizer Transaction includes milestone payments of $275.0 million upon the achievement of certain milestones. The 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 certain milestones we are obligated to make certain payments and have royalty obligations upon sales of products developed under the license agreements. At this time, we are unable to estimate the timing and amounts of payments as these are

(In thousands)	March 31, 2023	December 31, 2022
Assets:		
Pharmaceutical	$ 1,373,982	$ 1,322,531
Diagnostics	671,875	690,504
Corporate	123,813	154,224
	$ 2,169,670	$ 2,167,259
Goodwill:		
Pharmaceutical	$ 314,355	$ 312,826
Diagnostics	[illegible]	283,025
	$ 597,380	$ 595,851

No customer represented more than 10% of our total consolidated revenue during the three months ended March 31, 2023 and 2022. As of March 31, 2023 and December 31, 2022, no customer represented more than 10% of our accounts receivable balance.

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

	Three months	°	ين	Ĉ	Ĉ	كد	٤

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”).

In February 2018, in a transaction exempt from registration under the Securities Act, we issued the 2023 Convertible Notes in the aggregate principal amount of $55.0 million maturing, with an original maturity date in February 2023. Each holder of a 2023 Convertible Note hashad the option, from time to time, to convert all or any portion of the outstanding principal balance of such 2023 Convertible Note, together with accrued and unpaid interest thereon, into shares of our Common Stock, par value $0.01 pdat initial 5.0%

The following table provides information as of March 31, 2023, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining nine months ending December 31, 2023	2024	2025	2026	2027	Thereafter	Total
Open purchase orders	$ 52,568	$ 236	$ 5	$ —	$ —	$ —	$ 52,809
Operating leases	9,041	7,924	4,798	3,494	3,234	9,461	37,952
Finance leases	2,266	2,602	2,013	1,398	587	1,992	10,858
2025 and 2023 Convertible Notes	—	—	211,328	—	—	—	211,328
Mortgages and other debts payable	2,007	1,913	1,565	1,347	1,090	4,727	12,649
Lines of credit	22,259	—	—	—	—	—	22,259
Interest commitments	5,281	6,789	5,867	207	205	615	18,964
Total	$ 93,422	$ 19,464	$ 225,576	$ 6,446	$ 5,116	$ 16,795	$ 366,819

The preceding table does not include information where the amounts of the obligations are not currently determinable, including the following:

- Contractual here the t able

concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than three months.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are, from time to time, party to various legal proceedings arising out of our business. Except as described below, during the reporting period covered by this Quarterly Report on Form 10-Q, there have been no material changes to the description of legal proceedings set forth in our Annual Report on Form 10-K for the year ended December 31, 2022. The following should be read in conjunction with the information provided in Part I, Item 3 of such Annual Report on Form 10-K.

In February 2023, the Office of the Attorney General for the S£i £“prṕm aS ae Ď Þ

Item 1A. Risk Factors

There have been no material changes to ou

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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.

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. OMISSIONS ARE IDENTIFIED AS [***]

Exhibit 10.1

LICENSE AND RESEARCH COLLABORATION AGREEMENT

by and between

MODEX THERAPEUTICS, INC.,

OPKO HEALTH, INC.
(solely for purposes of sections 6.1 and 9.3)

and

MERCK SHARP & DOHME LLC

Effective March 7, 2023

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CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. OMISSIONS ARE IDENTIFIED AS [***]

1.19 "**Code**" shall have the meaning set forth in Section 8.4.5.

1.20 "**Combination Product**" shall mean a Product that includes one or more Vaccines in combination with one or more other clinically active components ***. All references to Product in this Agreement shall be deemed to include Combination Product.

1.21 "**Commercial Milestone Event**" shall have the meaning set forth in Section 5.2.2.

1.22 "**Commercial Milestone Payments**" shall have the meaning set forth in Section 5.2.2.

1.23 "**Commercialize**", or "**Commercializing**" or "**Commercialization**" shall mean to promote, market, distribute, import, export, sell, offer for sale, provide commercial-related product support for, and perform medical affairs activities for, a pharmaceutical product (including a Product or Vaccine).

1.24 "**Commercially Reasonable Efforts**" shall mean, with respect to the efforts to be expended by a Party with respect to any objective, such reasonable and diligent efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed *** such efforts shall be and other relevant factors. Commercially Reasonable Efforts shall be determined *** and the market(s) involved.

1.25 "**Committee**" shall mean the joint steering committee established to facilitate the Research Program, as more

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1.81 "**ModeX Third-Party License Agreement**" shall mean any agreement between ModeX or any of its Affiliates and any Third Party pursuant to which ModeX or its Affiliate in-licenses or otherwise acquires Control of any Know-How, Patent Rights, or other intellectual property rights that are or would constitute ModeX Know-How or ModeX Patent Rights under this Agreement, including the Sanofi In-License Agreement (defined below).

1.82 "**NDA**" shall mean a New Drug Application, Biologics License Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the Act, or similar application or submission for Marketing Authorization c

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1.90 "**Payment**" shall have the meaning set forth in Section 2.10.3.

1.91 "**Person**" shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any other entity not specifically listed herein.

1.92 "**Phase I Clinical Trial**" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(a).

1.93 "**Phase II Clinical Trial**" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(b).

1.94 "**Phase III Clinical Trial**" shall mean a human clinical trial in any country that would satisfy the requirements of 21 CFR 312.21(c).

1.95 "**Prior Non-Disclosure Agreement**" shall have the meaning set forth in Section 4.7.

1.96 "**Product(s)**" shall mean any pharmaceutical or biological preparation in final form containing a Vaccine (a) for sale by prescription, over-the-counter or any other method; or (b) for administration to human patients in a Clinical Trial, for any and all uses in the Field, including any Combination Product.

1.97 "**Regulatory Authority**" shall mean any an l m

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experience as are required to accomplish the Research Program in accordance with the terms of this Agreement and the applicable Research Plan. Merck shall be entitled to utilize the services of its Affiliates and Third Parties to perform its Research Program activities. ModeX shall be entitled to utilize the service of Third-Party subcontractors to perform its Research Program activities only upon Merck's prior written consent (which may be via email, or in the form of unanimous approval of the Committee) or as specifically set forth in the Research Plan. Notwithstanding any such consent, each Party shall remain at all times fully liable for its respective responsibilities under the Research Program.

2.3 **Joint Steering Committee**. The Parties hereby establish a committee to facilitate the Research Program, as follows:

2.3.1 **Composition of the Joint Steering Committee.** [illegible]

2.3.4 **Limit on Committee Actions**. Notwithstanding the foregoing, the Committee shall not have the authority to: (a) modify or amend the terms and conditions of this Agreement; (b) waive either Party's compliance with the terms and conditions of this Agreement; (c) determine any issue in

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3.2 **License Grants to ModeX**.

3.2.1 Merck hereby grants to ModeX, during the Research Term, a non-exclusive, non-sublicensable (other than ordinary-course nonexclusive sublicenses to permitted subcontractors performing activities hereunder on ModeX's behalf), royalty-free license under the Merck Know-How, Merck Patent Rights, and Merck Information and Inventions, solely to the extent necessary to perform ModeX's obligations under this Agreement (including the Research Plan).

3.2.2 Merck hereby grants to ModeX a non-exclusive, sublicensable (through multiple tiers), irrevocable, fully-paid license under (a) Merck Information and Inventions describing Improvements (including materials embodying Improvements) to the ModeX Platform, and (b) Patent Rights of Merck Information and Inventions that claim Improvements to the ModeX Platform, in the Territory, solely to research, develop, Manufacture, and Commercialize vaccines and products (that do not constitute Vaccines or Products) outside of the EBV Field. For clarity, in the event of any conflict, the license granted pursuant to this Section 3.2.2 shall in all cases be subject to the licenses granted by ModeX to Merck under this Agreement pursuant to Section 3.1.

3.3 **No Implied Licenses**.

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(a) Each Development Milestone Payment shall be payable only once, upon the first instance when the corresponding Development Milestone Event occurs, notwithstanding any subsequent achievement of the corresponding Development Milestone Event with respect to the same Vaccine or Product or a different Vaccine or Product.

(b) If any Development Milestone Event is achieved prior to the payment of an "earlier" milestone event (*e.g.*, if *** occurs prior to the payment of the Development Milestone Payment associated with ***, or if *** to payment of the Development Milestone Payment associated with ***), both Development Milestone Payments shall be payable simultaneously.

(c) Merck shall notify ModeX within *** following the achievement of such Development Milestone Event and shall make the appropriate Development Milestone Payment within *** following such achievement.

(d) The Development Milestone Event associated with *** shall be deemed achieved when ***.

(e) Concurrently with ***, Merck shall make the appropriate Commercial Milestone Payment. All milestone payments hereunder are non-refundable and non-creditable.

5.3 **Royalties**.

5.3.1 **Royalties Payable by Merck**. Subject to the terms and conditions of this Agreement, during the Royalty Period, Merck shall pay ModeX royalties, calculated on a Product-by-Product basis, as set forth in this Section 5.3.

(a) Patent Royalties. Subject to the provisions of Section 5.3.1(b), during the Royalty Period, Merck shall pay ModeX royalties in an amount equal to the following percentage of Net Sales of Products in the Territory by Merck or its Related Parties where the ***:

Net Sales Threshold	**Royalty Rate**
The portion of Net Sales ***	***
The portion of Net Sales ***	***
The portion of Net Sales ***	***

(b) *** Royalty. Notwithstanding the provisions of Section 5.3.1(a), in countries where a Product ***, during the Royalty Period, Merck shall pay royalties, on a *** of the applicable royalty rate set forth in Section 5.3.1(a). Such royalties shall be calculated after first calculating royalties under Section 5.3.1(a).

(c) Royalty Tiers. Royalty tiers pursuant to Section 5.3.1(a) and Section 5.3.1(b) shall be a

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Party, not to be unreasonably withheld or delayed. If the Parties cannot agree as to the application of Section 6.5.1 or Section 6.5.2 to any claim, pending resolution of the dispute pursuant to Section 9.8, the Parties may conduct separate defenses of such claims, with each Party retaining the right to claim indemnification from the other Party in accordance with Section 6.5.1 or Section 6.5.2 upon resolution of the underlying claim.

6.5.4 [illegible]. ***.

ARTICLE 7
PATENT PROVISIONS

7.1 **Filing, Prosecution and Maintenance of Patents**

7.1.1 **Modex Patent Rights.**

(a) ModeX First Right to File ModeX Patent Rights. ModeX shall have the first right to initially file provisional and international patent applications claiming ModeX Information and Inventions in the Territory, upon appropriate consultation with Merck using mutually agreeable outside counsel, ***. ModeX shall give Merck an opportunity to review the text of any patent application before filing, shall consult with Merck with respect thereto, shall incorporate any of Merck's comments thereto, and shall supply Merck with a copy of the application as filed, [illegible]

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(f) Option of ModeX to Prosecute and Maintain ModeX Patent Rights. Notwithstanding Section 7.1.1(b) or (c), on a country-by-country basis in the Territory, Merck shall give notice to ModeX of any desire to cease prosecution or maintenance of any ModeX Patent Rights and, in such cases, shall permit ModeX, in its sole discretion, to (on a country-by-country basis) continue prosecution or maintenance of such ModeX Patent Rights ***. In such events, if ModeX desires to continue prosecution or maintenance of such ModeX Patent Rights, Merck shall execute such documents and perform such acts as may be reasonably necessary for ModeX to perform such prosecution or maintenance, and ModeX shall control the prosecution and maintenance of such ModeX Patent Rights in such country(ies). For clarity, any such ModeX Patent Rights which are prosecuted and maintained by Merck in a particular country as permitted herein ***.

7.1.2 **Joint Patent Rights**. Subject to Section 7.1.5, Merck shall have the first right to file, prosecute, and maintain patents and patent applications claiming Joint Information and Inventions. Merck shall keep ModeX advised of the status of any actual and prospective patent filings and upon ModeX's request, shall provide advance copies of any papers related to the filing of Joint Information and Inventions and the prosecution and maintenance of Joint Patent Rights. Merck shall give notice to ModeX of any desire to cease prosecution or maintenance of Joint Patent Rights on a country-by-country basis in the Territory and, in such case, shall permit ModeX, in its sole discretion, to continue prosecution or maintenance of such Joint Patent Rights ***. If ModeX elects to continue prosecution or maintenance of such Joint Patent Rights, Merck shall execute documents in a timely manner as may be reasonably necessary to allow ModeX to continue such prosecution or maintenance.

7.1.3 **Merck Patent Rights**. Merck shall have the sole right to file, prosecute, and maintain the Merck Patent Rights and any patents and patent applications claiming Merck Information and Inventions.

7.1.4 **Patent Term Extension**. The Parties shall cooperate fully with each other to provide necessary information and assistance, as the other Party may reasonably request, in obtaining patent term extension or supplemental protection certificates or their equivalents in any country in the Territory where applicable Ğ

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or similar contested administrative proceeding involving a Third Party relating to ModeX Patent Rights or X

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8.2 **Termination by Merck for Convenience** . Notwithstanding anything contained herein to the contrary, Merck shall have the right to terminate this Agreement in its entirety at any time in its sole discretion by giving *** days' advance written notice to ModeX. For the avoidance of doubt, termination by Merck under this Section 8.2 can be effected only through a written notice specifically referring to this section.

8.3 **Termination for Cause**. This Agreement may be terminated at any time during the Term:

(a) upon written notice by either Party if the other Party is in breach of its material obligations hereunder and, if such breach is capable of cure, has not cured such breach within *** days after notice requesting cure of the breach (or immediately upon such written notice if such breach is incapable of cure); provided, in the event of a good faith dispute with respect to the existence of a material breach or whether such breach is capable of cure, the termination or *** day cure period (if applicable) shall be tolled until such time as the dispute is resolved pursuant to Section 9.8; or

(b) by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within *** days after the filing thereof.

8.4 **Effects of Termination**.

8.4.1 **Generally**. If this Agreement is terminated for any reason, the following shall apply:

(a) No later than *** days after the effective date of such termination, each Party shall return or cause to be returned to the other Party all Information in tangible form received from the other Party and all copies thereof; provided, that ***.

(b) Each Party shall pay all amounts then due and owing as of the termination date.

(c) Except for the surviving provisions set forth in Section 8.5, the rights and obligations of the Parties hereunder, including ***, shall terminate as of the date of such termination; provided, that (i) Merck shall have a fully paid-up non-exclusive license to use ModeX Information and Inventions and ModeX's interest in Joint Information and Inventions, in each case for *** purposes only, and (ii) Merck and its Affiliates, sublicensees, and distributors shall be entitled, during the *** month period immediately following the effective date of termination, to finish any work-in-progress and to sell any Product or Vaccine remaining in inventory, in accordance with the terms of this Agreement. Upon termination, the Parties shall confer to determine how the Joint Patent Rights will be addressed.

8.4.2 **Effects of Termination by Merck for Convenience or by ModeX for Cause** . If Merck terminates this Agreement pursuant to Section 8.2 or ModeX terminates this Agreement pursuant to Section 8.3(a), the following shall apply:

(a) ModeX may elect by delivery of notice to Merck no later than *** Business Days after the effective date of such termination, and Merck hereby grants, contingent upon such election by ModeX but effective upon such termination, a non-exclusive, royalty-bearing, sublicensable (through multiple tiers) license (the "**Reversion License**") under (***, in each case, ***, and (ii) ***, in each case (of (i) and (ii)): (A) ***, and (B) solely for ModeX to Develop, Manufacture, and Commercialize Vaccines and Products which have not been terminated by Merck for a Material Safety Issue (such Vaccines and Products, the "**Reverted Products**").

(b) Notwithstanding the foregoing, (i) the ***; and (ii) to the extent that any ***.

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(c) The Parties shall use reasonable efforts to agree, within *** days after the effective date of the termination, to *** shall not *** (and shall be subject to ***, *mutatis mutandis*).

(d) ***, following delivery of ***. *** agree to include any such ***.

(e) *** shall cooperate with and provide timely assistance to *** to to ensure the reasonable *** for the provision of any transition services included. Such *** shall include a ***.

(f) *** after receiving notice of *** as may be necessary e necessao

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ARTICLE 9
MISCELLANEOUS

9.1 **Force Majeure**. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical and shall promptly undertake all reasonable efforts necessary to cure such force majeure circumstances.

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Business Day, then on the next Business Day); (b) on the Business Day after dispatch if sent by nationally recognized overnight courier; or (c) on the fifth (5th) Business Day following the date i g

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IN WITNESS WHEREOF, the undersigned have executed and delivered this Agreement as of the date first set forth above.

MERCK SHARP & DOHME LLC

BY: /s/ David A. Paveli

MODEX THERAPEUTICS, INC.

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EXHIBIT A

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SCHEDULE 1.63

***

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SCHEDULE 1.81

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SCHEDULE 6.2.7

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SCHEDULE 6.3.2

***

Exhibit 31.1

CERTIFICATIONS

I, Phillip Frost, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health, Inc.;

(2) Based on my knowledge, this report does no P

Exhibit 31.2

CERTIFICATIONS

I, Adam Logal, certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 3, 2023

/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, 2023 (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.

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-Ox(dı giCN x6 Sa r. dd. op