UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2023.

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission file number 001-33528

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**75-2402409**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**

4400 Biscayne Blvd.
Miami FL 33137

(Address of Principal Executive Offices) (Zip Code)

(305) 575-4100

(Registrant's Telephone Number, Including Area Code)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

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 (as defined in Rule 12b-2 of the Exchange Act): ☐ Yes ☒ No

As of April 27, 2023, the registrant had 772,650,812 shares of Common Stock outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended (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, 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, 2022, and described from time to time in our other filings with the Securities and Exchange Commission (the "SEC"). We do not undertake any obligation to update forward-looking statements, except to the extent required by applicable law. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Risks and uncertainties, the occurrence of which could adversely affect our business, include the following:

- we have had a history of losses and may not generate sustained positive cash flow sufficient to fund our operations and research and development programs;
- our need for, and ability to obtain, additional financing when needed on favorable terms, or at all;
- adverse results in material litigation matters or governmental inquiries;
- the risks inherent in developing, obtaining regulatory approvals for and commercializing new, commercially viable and competitive products and treatments;
- our research and development activities may not result in commercially viable products;
- that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results;
- that we may fail to obtain regulatory approval for Somatrogon (hGH-CTP) in the United States ("U.S.") and other territories in which we have applied, or successfully commercialize Somatrogon (hGH-CTP);
- our business may be materially adversely affected by the coronavirus (COVID-19) pandemic, including the impact from declines in testing needs as infection rates decline and the normalization of living with COVID-19 following the increase in accessibility to COVID-19 vaccines and antiviral treatments;
- that we may not generate or sustain profits or cash flow from our laboratory operations or substantial revenue from *Rayaldee* and our other pharmaceutical and diagnostic products;
- our ability to manage our growth and our expanded operations;
- that our acquisition of ModeX Therapeutics, Inc. will be successful and the products in the R&D pipeline will ultimately be commercialized;
- that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied;
- our ability and our distribution and marketing partners' ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates and the operation of our laboratories;
- the performance of our third-party distribution partners, licensees and manufacturers over which we have limited control;
- changes in regulation and policies in the U.S. and other countries, including increasing downward pressure on healthcare reimbursement;
- increased competition, including price competition;
- our success is dependent on the involvement and continued efforts of our Chairman and Chief Executive Officer;

- 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 *4Kscore* test;
- failure to timely or accurately bill and collect for our services;
- the information technology systems that we rely on may be subject to unauthorized tampering, cyberattack or other data security or privacy incidents that could impact our billing processes or disrupt our operations;
- failure to obtain and retain new clients and business partners, or a reduction in tests ordered or specimens submitted by existing clients;
- failure to establish, and perform to, appropriate quality standards to assure that the highest level of quality is observed in the performance of our testing services;
- failure to maintain the security of patient-related information;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to defend our intellectual property rights with respect to our products;
- our ability to operate our business without infringing the intellectual property rights of others;
- our ability to attract and retain key scientific and management personnel;
- the risk that the carrying value of certain assets may exceed the fair value of the assets causing us to impair goodwill or other intangible assets;
- our ability to comply with the terms of our 2022 Corporate Integrity Agreement with the U.S. Office of Inspector General of the Department of Health and Human Services;
- failure to obtain and maintain regulatory approval outside the U.S.; and
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations.

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)
(In thousands, except share and per share data)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 110,830	$ 153,191
Accounts receivable, net	121,486	127,312
Inventory, net	75,411	74,060
Other current assets and prepaid expenses	98,691	39,962
Total current assets	406,418	394,525
Property, plant and equipment, net	80,853	82,879
Intangible assets, net	803,616	823,520
In-process research and development	195,000	195,000
Goodwill	597,380	595,851
Investments	41,231	28,080
Operating lease right-of-use assets	36,832	38,725
Other assets	8,340	8,679
Total assets	$ 2,169,670	$ 2,167,259
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 80,503	$ 66,993
Accrued expenses	106,058	98,269
Current maturities of operating leases	11,490	11,628
Current portion of convertible notes	—	3,050
Current portion of lines of credit and notes payable	24,371	33,540
Total current liabilities	222,422	213,480
Operating lease liabilities	26,462	27,963
Long term portion of convertible notes	211,328	210,371
Deferred tax liabilities	129,668	126,426
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	27,980	27,371
Total long-term liabilities	395,438	392,131
Total liabilities	617,860	605,611
Equity:		
Common Stock - $0.01 par value, 1,000,000,000 shares authorized; 781,306,164 and 781,306,164 shares issued at March 31, 2023 and December 31, 2022, respectively	7,813	7,813
Treasury Stock - 8,655,082 shares at March 31, 2023 and December 31, 2022, respectively	(1,791)	(1,791)
Additional paid-in capital	3,424,589	3,421,872
Accumulated other comprehensive loss	(37,611)	(43,323)
Accumulated deficit	(1,841,190)	(1,822,923)
Total shareholders' equity	1,551,810	1,561,648
Total liabilities and equity	$ 2,169,670	$ 2,167,259

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

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

	For the three months ended March 31,	
	2023	2022
Revenues:		
Revenue from services	$ 132,368	$ 286,599
Revenue from products	40,383	36,658
Revenue from transfer of intellectual property and other	64,826	5,962
Total revenues	237,577	329,219
Costs and expenses:		
Cost of service revenue	114,059	221,202
Cost of product revenue	24,255	22,673
Selling, general and administrative	75,642	117,537
Research and development	32,605	18,312
Contingent consideration	136	(106)
Amortization of intangible assets	21,474	22,025
Total costs and expenses	268,171	401,643
Operating loss	(30,594)	(72,424)
Other income and (expense), net:		
Interest income	1,030	10
Interest expense	(3,391)	(2,662)
Fair value changes of derivative instruments, net	(1,059)	(132)
Other income (expense), net	17,017	(1,442)
Other income (expense), net	13,597	(4,226)
Loss before income taxes and investment losses	(16,997)	(76,650)
Income tax benefit (provision)	(1,233)	21,266
Net loss before investment losses	(18,230)	(55,384)
Loss from investments in investees	(37)	(49)
Net loss	$ (18,267)	$ (55,433)
Loss per share, basic and diluted:		
Loss per share	$ (0.02)	$ (0.08)
Weighted average common shares outstanding, basic and diluted	751,506,257	660,302,426

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

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

	For the three months ended March 31,	
	2023	2022
Net loss	$ (18,267)	$ (55,433)
Other comprehensive income (loss), net of tax:		
Change in foreign currency translation and other comprehensive income (loss)	5,712	(920)
Comprehensive loss	$ (12,555)	$ (56,353)

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

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	$ (30,495)	$ (1,511,976)	$ 1,685,126
Equity-based compensation expense	—	—	—	—	7,617	—	—	7,617
Exercise of common stock options and warrants	55,750	1	—	—	135	—	—	136
Adoption of ASU 2020-06	—	—	—	—	(39,100)	—	17,458	(21,642)
Net loss	—	—	—	—	—	—	(55,433)	(55,433)
Other comprehensive loss	—	—	—	—	—	(920)	—	(920)
Balance at March 31, 2022	690,138,033	$ 6,902	(8,655,082)	$ (1,791)	$ 3,191,139	$ (31,415)	$ (1,549,951)	$ 1,614,884

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

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

	For the three months ended March 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (18,267)	$ (55,433)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	26,446	27,814
Non-cash interest	678	678
Amortization of deferred financing costs	296	281
Losses from investments in investees	37	49
Equity-based compensation – employees and non-employees	2,717	7,617
Realized loss on disposal of fixed assets and sales of equity securities	1,845	61
Change in fair value of equity securities and derivative instruments	(7,130)	1,299
Change in fair value of contingent consideration	136	(106)
Deferred income tax benefit	102	(22,356)
Changes in assets and liabilities:		
Accounts receivable, net	7,364	44,421
Inventory, net	1,306	(9,463)
Other current assets and prepaid expenses	(58,902)	2,612
Other assets	772	511
Accounts payable	12,759	16,143
Foreign currency measurement	(2,355)	2,197
Contract liabilities	2	(4)
Accrued expenses and other liabilities	9,547	(36,177)
Net cash used in operating activities	(22,647)	(19,856)
Cash flows from investing activities:		
Investments in investees	(5,000)	—
Proceeds from the sale of property, plant and equipment	320	348
Capital expenditures	(3,037)	(5,251)
Net cash used in investing activities	(7,717)	(4,903)
Cash flows from financing activities:		
Proceeds from the exercise of common stock options	—	136
Borrowings on lines of credit	165,288	1,649,166
Repayments of lines of credit	(175,407)	(1,657,193)
Redemption of 2033 Senior Notes	(3,000)	—
Net cash used in financing activities	(13,119)	(7,891)
Effect of exchange rate changes on cash and cash equivalents	1,122	221
Net decrease in cash and cash equivalents	(42,361)	(32,429)
Cash and cash equivalents at beginning of period	153,191	134,710
Cash and cash equivalents at end of period	$ 110,830	$ 102,281
SUPPLEMENTAL INFORMATION:		
Interest paid	$ 3,830	$ 3,420
Income taxes paid, net of refunds	$ 477	$ 1,063
Assets acquired by finance leases	$ 960	$ —

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

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 GeneDx Holdings, pursuant to which the Company has agreed to, among other things, be subject to a lock-up period with respect to its shares of GeneDx Holdings Common Stock, which expired on April 29, 2023 with respect to the Closing Shares, and, if earned and received, would extend for periods of one-year and six-months from the date of issuance of such shares in respect of the first and second potential Milestone Consideration payments, respectively.

Pursuant to the GeneDx Merger Agreement, the Company designated, and GeneDx Holdings nominated for election an individual to serve on the board of directors of GeneDx Holdings, and such nominee was elected by GeneDx Holdings' stockholders to serve as a director at least until GeneDx Holdings' 2024 annual meeting of stockholders. In addition, the Company has further agreed to certain standstill provisions whereby, subject to certain exceptions, it is obligated to refrain from taking certain actions with respect to the GeneDx Holdings Common Stock. The Company has also agreed to vote its shares of GeneDx Holdings Common Stock in accordance with the recommendations of GeneDx Holdings's board of directors for so long as it continues to hold at least 5% of the outstanding shares of GeneDx Holdings Common Stock. Further, GeneDx Holdings has also granted the Company certain customary shelf, piggyback and demand registration rights that require GeneDx Holdings to register the shares of the Company's shares of GeneDx Holdings Common Stock for resale under the Securities Act. OPKO intends to have a designee serving on GeneDx Holdings's board of directors through the lock-up period applicable to the Company's shares of GeneDx Holdings Common Stock. Such designee may continue to sit on the GeneDx Holdings board if elected by the GeneDx Holdings stockholders.

NOTE 2 IMPACT OF COVID-19 AND FOREIGN EXCHANGE RATES

Impact of COVID-19

We continue to be a part of the coordinated public and private sector response to the COVID-19 pandemic. There continues to be a high level of uncertainty relating to the pandemic's continuing evolution, including how governments and consumers will react to new developments, and whether the pandemic will have a longer-term effect on the healthcare industry and patient habits. BioReference has been providing COVID-19 solutions, including diagnostic molecular testing and serology antibody testing, to meet the testing needs of its customers, including physicians, health systems, long-term care facilities, governments, schools, employers, professional sports teams and entertainment venues, as well as the general public through relationships with retail pharmacy chains.

Throughout the pandemic, we have managed our company-wide lab operations specimen acquisition, logistics, procurement, customer service, and initiatives to manage our cost structure to match the ever changing COVID-19 testing volumes and to identify and capitalize on efficiencies in our core clinical lines of business. While BioReference benefited from significant COVID-19 testing volumes in 2020 and 2021, demand declined in 2022 and continued to decline during the first quarter of 2023.

Revenue from services for the three months ended March 31, 2023 decreased by $154.2 million as compared to 2022 due to lower COVID-19 testing volumes. Excluding COVID-19 test volumes, for the three months ended March 31, 2023, routine clinical test volume increased 6.8% as compared to volumes for the three months ended March 31, 2022.

Foreign Currency Exchange Rates

Approximately 18.5% of revenue for the three months ended March 31, 2023, and approximately 10.9% of revenue for the three months ended March 31, 2022, were denominated in currencies other than the U.S. Dollar (USD). Our financial statements are reported in USD and, accordingly, fluctuations in exchange rates will affect the translation of revenues and

expenses denominated in foreign currencies into USD for purposes of reporting the consolidated financial results. In the first quarter of 2023 and the year ended December 31, 2022, the most significant currency exchange rate exposures were to the Euro and Chilean Peso. Gross accumulated currency translation adjustments recorded as a separate component of shareholders' equity were $34.2 million and $39.9 million at March 31, 2023 and December 2022, respectively.

We are subject to foreign currency transaction risk for fluctuations in exchange rates during the period of time between the consummation and cash settlement of transactions. We limit foreign currency transaction risk through hedge transactions with foreign currency forward contracts. Under these forward contracts, for any rate above or below the fixed rate, we receive or pay the difference between the spot rate and the fixed rate for the given amount at the settlement date. At March 31, 2023, we had 177 open foreign exchange forward contracts relating to inventory purchases on letters of credit with various amounts maturing monthly through April 2023 with a notional value totaling approximately $10.4 million. At December 31, 2022, we had 194 open foreign exchange forward contracts relating to inventory purchases on letters of credit with various amounts maturing monthly through January 2023 with a notional value totaling approximately $11.9 million.

NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation. The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments or adjustments otherwise disclosed herein) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three months ended March 31, 2023 are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2023 or any other future periods. The unaudited Condensed Consolidated Financial Statements should be read in conjunction with the audited Consolidated Financial Statements and the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Principles of consolidation. The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of OPKO Health, Inc. and our wholly-owned subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

Use of estimates. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and 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 months ended March 31, 2023 and 2022, was $1.4 million and $1.3 million, respectively.

Goodwill and intangible assets. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired accounted for by the acquisition method of accounting. Refer to Note 5. Goodwill, in-process research and development ("IPR&D") and other intangible assets acquired in business combinations, licensing and other transactions was $1.6 billion at March 31, 2023 and December 31, 2022.

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. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. At acquisition, we generally determine the fair value of intangible assets, including IPR&D, using the "income method."

Subsequent to their acquisition, goodwill and indefinite lived intangible assets are tested at least annually as of October 1 for impairment, or when events or changes in circumstances indicate it is more likely than not that the carrying amount of such assets may not be recoverable.

Estimating the fair value of a reporting unit for goodwill impairment is highly sensitive to changes in projections and assumptions and changes in assumptions could potentially lead to impairment. We perform sensitivity analyses around our assumptions in order to assess the reasonableness of the assumptions and the results of our testing. Ultimately, potential changes in these assumptions may impact the estimated fair value of a reporting unit and result in an impairment if the fair value of such reporting unit is less than its carrying value. Goodwill was $597.4 million and $595.9 million, respectively, at March 31, 2023 and December 31, 2022.

Net intangible assets other than goodwill was $1.0 billion on March 31, 2023, and December 31, 2022, respectively, including IPR&D of $195.0 million on March 31, 2023, and December 31, 2022. Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products and IPR&D. Considering the high risk nature of research and development and the industry's success rate of bringing developmental compounds to market, IPR&D impairment charges may occur in future periods. Estimating the fair value of IPR&D for potential impairment is highly sensitive to changes in projections and assumptions and changes in assumptions could potentially lead to impairment.

Upon obtaining regulatory approval, IPR&D assets are then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the IPR&D asset is charged to expense. Finite lived intangible assets are tested for impairment when events or changes in circumstances indicate it is more likely than not that the carrying amount of such assets may not be recoverable. The testing includes a comparison of the carrying amount of the asset to its estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

We believe that our estimates and assumptions in testing goodwill and other intangible assets, including IPR&D, for impairment are reasonable and otherwise consistent with assumptions that marketplace participants would use in their estimates of fair value. Based on the current financial performance of our diagnostic segment, if future results are not consistent with our estimates and assumptions, then we may be exposed to impairment charges, which could be material. In our pharmaceutical segment, Pfizer submitted the initial 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 determine the best path forward for Somatrogon (hGH-CTP) in the United States. If we are unable to get approval for Somatrogon (hGH-CTP) in the United States, then we may be exposed to impairment charges, which could be material.

In 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.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense was $21.5 million and $22.0 million for the three months ended March 31, 2023 and 2022, respectively.

Fair value measurements. The carrying amounts of our cash and cash equivalents, accounts receivable, accounts payable and short-term debt approximate their fair value due to the short-term maturities of these instruments. Investments that are considered equity securities as of March 31, 2023 and December 31, 2022 are predominately carried at fair value. Our debt under the Credit Agreement (as defined below) approximates fair value due to the variable rate of interest applicable to such debt.

In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts. Accordingly, the estimates of fair value presented herein may not be indicative of the amounts that could be realized in a current market exchange. Refer to Note 9.

Contingent consideration. Each period we revalue the contingent consideration obligations associated with certain prior acquisitions to their fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as a reduction in contingent consideration expense. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as our development programs progress, revenue estimates evolve and additional data is obtained, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value which may have a material impact on our results from operations and financial position.

Derivative financial instruments. We record derivative financial instruments on our Condensed Consolidated Balance Sheet at their fair value and recognize the changes in the fair value in our Condensed Consolidated Statement of Operations when they occur, the only exception being derivatives that qualify as hedges. For the derivative instrument to qualify as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At March 31, 2023 and December 31, 2022, our foreign currency forward contracts held to economically hedge inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognized all changes in the fair values of our derivatives instruments, net, in our Condensed Consolidated Statement of Operations. Refer to Note 10.

Property, plant and equipment. Property, plant and equipment are recorded at cost or fair value if acquired in a business combination. Depreciation is provided using the straight-line method over the estimated useful lives of the assets and includes amortization expense for assets capitalized under finance leases. The estimated useful lives by asset class are as follows: software - 3 years, machinery, medical and other equipment - 5-8 years, furniture and fixtures - 5-12 years, leasehold improvements - the lesser of their useful life or the lease term, buildings and improvements - 10-40 years, and automobiles - 3-5 years. Expenditures for repairs and maintenance are charged to expense as incurred. Assets held under finance leases are included within Property, plant and equipment, net in our Condensed Consolidated Balance Sheets and are amortized over the shorter of their useful lives or the expected term of their related leases. Depreciation expense was $5.0 million and $5.8 million for the three months ended March 31, 2023, and 2022, respectively.

Impairment of long-lived assets. Long-lived assets, such as property and equipment and assets held for sale, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Income taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of 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 three months ended March 31, 2023, 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.

Included in Other long-term liabilities is an accrual of $6.0 million related to uncertain tax positions involving income recognition. In connection with an examination of foreign tax returns for the 2014 through 2020 tax years, a foreign taxing authority has issued an income tax assessment of approximately $246 million (including interest). We are appealing this assessment, as we believe, other than for uncertain tax positions for which we have reserved, the issues are without technical merit. We intend to exhaust all judicial remedies necessary to resolve the matter, as necessary, which could be a lengthy process. There can be no assurance that this matter will be resolved in our favor, and an adverse outcome, or any future tax examinations involving similar assertions, could have a material adverse effect on our financial condition, results of operations and cash flows.

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. For a complete discussion of accounting for Revenues from services, Revenues from products and Revenue from transfer of intellectual property and other, refer to Note 13.

Concentration of credit risk and allowance for credit losses. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of accounts receivable. Substantially all of our accounts receivable are with either companies in the healthcare industry or patients. However, credit risk is limited due to the number of our clients as well as their dispersion across many different geographic regions.

While we have receivables due from federal and state governmental agencies, such receivables are not a credit risk because federal and state governments fund the related healthcare programs. Payment is primarily dependent upon submitting appropriate documentation. On March 31, 2023 and December 31, 2022, receivable balances (net of explicit and implicit price concessions) from Medicare and Medicaid were 14% and 14%, respectively, of our consolidated Accounts receivable, net.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At March 31, 2023 and December 31, 2022, receivables due from patients represented approximately 3.3% and 2.9%, respectively, of our consolidated Accounts receivable, net.

We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer's ability to pay. Actual results could differ from those estimates. The allowance for credit losses was $2.1 million and $4.2 million on March 31, 2023, and December 31, 2022, respectively. The credit loss expense for the three months ended March 31, 2023 and 2022, was $85.2 thousand and $87.6 thousand, respectively.

Equity-based compensation. We measure the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits realized from the exercise of stock options as cash flows from operations. For the three months ended March 31, 2023 and 2022, we recorded $2.7 million and $7.6 million, respectively, of equity-based compensation expense.

Research and development expenses. Research and development expenses include external and internal expenses. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. Research and development employee-related expenses include 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. We expense these costs in the period in which they are incurred. We estimate our liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon our estimate of services received and degree of completion of the services in accordance with the specific third party contract.

Research and development expense includes costs for in-process research and development projects acquired in asset acquisitions which have not reached technological feasibility, and which have no alternative future use. For in-process research and development projects acquired in business combinations, the in-process research and development project is capitalized and evaluated for impairment until the development process has been completed. Once the development process has been completed the asset will be amortized over its remaining estimated useful life.

Segment reporting. Our chief operating decision-maker ("CODM") is Phillip Frost, M.D., our Chairman and Chief Executive Officer. Our CODM reviews our operating results and operating plans and makes resource allocation decisions on a Company-wide or aggregate basis. We manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of our pharmaceutical operations in Chile, Mexico, Ireland, Israel and Spain, *Rayaldee* product sales and our pharmaceutical research and development. The diagnostics segment primarily consists of clinical and genomics laboratory operations through BioReference and point-of-care operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense or income taxes. Refer to Note 15.

Shipping and handling costs. We do not charge customers for shipping and handling costs. Shipping and handling costs are classified as Cost of revenues in the Condensed Consolidated Statement of Operations.

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. We have made strategic investments in development stage and emerging companies. We record these investments as equity method investments or as equity securities based on our percentage of ownership and whether we have significant influence over the operations of the investees. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Losses from investments in investees in our Condensed Consolidated Statement of Operations. Refer to Note 6. For investments classified as equity securities, we record changes in their fair value as Other income (expense) in our Condensed Consolidated Statement of Operations based on their closing price per share at the end of each reporting period, unless the equity security does not have a readily determinable fair value. Refer to Note 6.

Recently adopted accounting pronouncements.

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)." ASU 2020-06 simplifies the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. The ASU is effective for public entities for fiscal years beginning after December 15, 2021, with early adoption permitted. As required, we adopted ASU 2020-06 on January 1, 2022 and used the modified retrospective approach for all convertible debt instruments at the beginning of the period of adoptions. Results for reporting periods beginning January 1, 2022 are presented under ASU 2020-06, while prior period amounts were not adjusted and continue to be reported in accordance with historic accounting guidance.

Under the modified approach, entities will apply the guidance to all financial instruments that are outstanding as of the beginning of the year of adoption with the cumulative effect recognized as an adjustment to the opening balance of retained earnings. ASU 2020-06 eliminates the cash conversion and beneficial conversion feature models in ASC 470-20 that require an issuer of certain convertible debt and preferred stock to separately account for embedded conversion features as a component of equity. The adoption of ASU 2020-06 at January 1, 2022 resulted in an increase of the Convertible notes of $21.6 million, a reduction of the Accumulated deficit of $17.5 million and a reduction of Additional paid-in capital of $39.1 million.

NOTE 4 EARNINGS (LOSS) PER SHARE

Basic income (loss) per share is computed by dividing our net income (loss) by the weighted average number of shares of our Common Stock outstanding during the period. Shares of Common Stock outstanding under the share lending arrangement entered into in conjunction with the 2025 Notes (as defined in Note 7) are excluded from the calculation of basic and diluted earnings per share because the borrower of the shares is required under the share lending arrangement to refund any dividends paid on the shares lent. Refer to Note 7. For diluted earnings per share, the dilutive impact of stock options and warrants is determined by applying the "treasury stock" method. The dilutive impact of the 2033 Senior Notes, the 2023 Convertible Notes and the 2025 Notes (each, as defined and discussed in Note 7) has been considered using the "if converted" method. For periods in which their effect would be antidilutive, no effect is given to Common Stock issuable under outstanding options or warrants or the potentially dilutive shares issuable pursuant to the 2033 Senior Notes, the 2023 Convertible Notes and the 2025 Notes in the dilutive computation.

A total of 82,441,440 and 57,985,925 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the three months ended March 31, 2023 and 2022, respectively, because their inclusion would be antidilutive. A full presentation of diluted earnings per share has not been provided because the required adjustments to the numerator and denominator resulted in diluted earnings per share equivalent to basic earnings per share.

During the three months ended March 31, 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

(In thousands)	March 31, 2023	December 31, 2022
Accounts receivable, net:		
Accounts receivable	$ 123,553	$ 131,474
Less: allowance for credit losses	(2,067)	(4,162)
	$ 121,486	$ 127,312
Inventories, net:		
Consumable supplies	$ 30,176	$ 31,275
Finished products	39,260	37,139
Work in-process	2,897	2,449
Raw materials	7,671	6,771
Less: inventory reserve	(4,593)	(3,574)
	$ 75,411	$ 74,060
Other current assets and prepaid expenses:		
Taxes recoverable	$ 7,653	$ 8,191
Prepaid expenses	9,058	7,918
Prepaid insurance	1,628	4,496
Other receivables	74,271	13,105
Other	6,081	6,252
	$ 98,691	$ 39,962
Intangible assets, net:		
Customer relationships	$ 315,586	$ 314,854
Technologies	829,021	826,282
Trade names	49,767	49,752
Covenants not to compete	12,913	12,911
Licenses	6,100	5,988
Product registrations	7,176	6,831
Other	5,934	5,861
Less: accumulated amortization	(422,881)	(398,959)
	$ 803,616	$ 823,520
Accrued expenses:		
Inventory received but not invoiced	$ 7,830	$ 7,830
Commitments and contingencies	4,006	4,295
Employee benefits	40,323	33,765
Clinical trials	5,708	4,700
Contingent consideration	65	62
Finance leases short-term	2,968	2,809
Professional fees	2,041	1,820
Other	43,117	42,988
	$ 106,058	$ 98,269
Other long-term liabilities:		
Contingent consideration	$ 1,114	$ 974
Mortgages and other debts payable	8,801	9,098
Finance leases long-term	7,890	7,089
Contract liabilities	140	138
Other	10,035	10,072
	$ 27,980	$ 27,371

Our intangible assets and goodwill relate principally to our completed acquisitions of OPKO Renal, OPKO Biologics, EirGen, BioReference and ModeX. We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives. The estimated useful lives by asset class are as follows: technologies - 7-17 years, customer relationships - 5-20 years, product registrations - 7-10 years, covenants not to compete - 5 years, trade names - 5-10 years, other 9-13 years. We do not anticipate capitalizing the cost of product registration renewals, rather we expect to expense these costs, as incurred. Our goodwill is not tax deductible for income tax purposes in any jurisdiction in which we operate.

In 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 (hGH-CTP)) in Europe and Japan. The assets will be amortized on a straight-line basis over their estimated useful life of approximately 12 years. Other changes in value of the intangible assets and goodwill during the three months ended March 31, 2023 and 2022 were primarily due to foreign currency fluctuations between the Euro, and the Chilean Peso against the U.S. dollar.

The following table summarizes the changes in Goodwill by reporting unit during the three months ended March 31, 2023.

	2023				
(In thousands)	Gross goodwill at January 1	Cumulative impairment at January 1	Acquisitions, dispositions and other	Foreign exchange and other	Balance at March 31
Pharmaceuticals					
CURNA	$ 4,827	$ (4,827)	$ —	$ —	$ —
Rayaldee	81,786	—	—	1,304	83,090
FineTech	11,698	(11,698)	—	—	—
ModeX	80,432	—	(173)	—	80,259
OPKO Biologics	139,784	—	—	—	139,784
OPKO Chile	3,767	—	—	284	4,051
OPKO Health Europe	7,057	—	—	114	7,171
OPKO Mexico	100	(100)	—	—	—
Transition Therapeutics	3,421	(3,421)	—	—	—
Diagnostics					
BioReference	283,025	—	—	—	283,025
OPKO Diagnostics	17,977	(17,977)	—	—	—
	$ 633,874	$ (38,023)	$ (173)	$ 1,702	$ 597,380

NOTE 6 ACQUISITIONS AND INVESTMENTS

ModeX Acquisition

On May 9, 2022, the Company entered into the ModeX Merger Agreement, pursuant to which ModeX became a wholly owned subsidiary of the Company. The Company paid the entirety of the $300.0 million purchase price pursuant to the issuance of the Consideration Shares to the former stockholders of ModeX. The Consideration Shares were valued at $219.4 million, based on the closing price per share of our Common Stock of $2.44 as reported by NASDAQ on the Closing Date. Included in the total purchase price of $221.7 million were $2.3 million of fully vested equity awards.

The following table summarizes the preliminary purchase price allocation and the estimated fair value of the net assets acquired and liabilities assumed at the date of acquisition. The purchase price allocation for the ModeX transaction is preliminary pending completion of the fair value analysis of acquired assets and liabilities:

(in thousands)	ModeX
Cash and cash equivalents	$ 228
Other assets	727
Property, plant and equipment	1,046
IPR&D assets	195,000
Goodwill	80,260
Accounts payable	(287)
Deferred tax liability	(55,312)
Total purchase price	$ 221,662

Goodwill from the acquisition of ModeX principally relates to intangible assets that do not qualify for separate recognition (for instance, ModeX's assembled workforce) and the deferred tax liability generated as a result of the transaction. Goodwill is not tax deductible for income tax purposes and was assigned to the pharmaceutical reporting segment.

Our IPR&D assets will not be amortized until the underlying development programs are completed and we obtain regulatory approval. The IPR&D asset is then accounted for as a finite-lived intangible asset and amortized depending on pattern of future use. Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the project is completed or abandoned.

Since the date of acquisition, ModeX has recorded revenue of $50.0 million and accumulated net income of $19.5 million. Net loss in the Condensed Consolidated Statement of Operations for the three months ended March 31, 2023, includes $30.2 million of net income from ModeX.

Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of March 31, 2023 and December 31, 2022:

(in thousands)	As of March 31, 2023		As of December 31, 2022	
Investment type	Investment Carrying Value	Underlying Equity in Net Assets	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	$ 69	$ 3,340	$ 103	$ 4,120
Variable interest entity, equity method	798	1,368	800	1,370
Equity method investments - FV option	34,414		21,120	
Equity securities	543		648	
Equity securities with no readily determinable fair value	5,381		5,381	
Warrants and options	26		28	
Total carrying value of investments	$ 41,231		$ 28,080	

Equity method investments

Our equity method investments, other than GeneDx Holdings disclosed below, consist of investments in Pharmsynthez (ownership 9%), Cocrystal Pharma, Inc. (“COCP”) (3%), Non-Invasive Monitoring Systems, Inc. (“NIMS”) (1%), Neovasc, Inc. (“Neovasc”) (0.5%), BioCardia, Inc. (“BioCardia”) (1%), Xenetic Biosciences, Inc. (“Xenetic”) (3%), and LeaderMed Health Group Limited (“LeaderMed”) (47%). The aggregate amount of assets, liabilities, and net losses of these equity method investees as of and for the three months ended March 31, 2023 were $144.0 million, $47.0 million, and $24.9 million, respectively. The aggregate amount of assets, liabilities, and net losses of our equity method investees as of and for the year ended December 31, 2022 were $167.1 million, $46.5 million, and $101.5 million, respectively. We have determined that we or our related parties have the ability to exercise significant influence over our equity method investments through our board representation or voting power. Accordingly, we account for our investment in these entities under the equity method and record our proportionate share of their losses in Loss from investments in investees in our Consolidated Statement of Operations. The aggregate value of our equity method investments based on the quoted market prices of their respective shares

of common stock and the number of shares held by us as of March 31, 2023 and December 31, 2022 was $1.5 million and $1.3 million, respectively.

Equity method investments - Fair value option

On April 29, 2022, the Company sold GeneDx to GeneDx Holdings in accordance with the terms of the GeneDx Merger Agreement, pursuant to which GeneDx Holdings paid to the Company aggregate consideration of $150.0 million in cash (before deduction of transaction expenses and other customary purchase price adjustments), together with the Closing Shares. In January 2023, we purchased 14,285,714 shares of GeneDx Holdings Common Stock for an aggregate of $5.0 million in GeneDx Holdings' underwritten public offering.. As of March 31, 2023, we held 94.3 million shares of GeneDx Holdings Common Stock, representing an approximate 11.8% ownership interest.

Pursuant to the GeneDx Merger Agreement, the Company designated, and GeneDx Holdings nominated for election an individual to serve on the board of directors of GeneDx Holdings, and such nominee was elected by GeneDx Holdings stockholders to serve as a director until GeneDx Holdings 2024 annual meeting of stockholders. As a result, we have determined that the Company or our related parties can exercise significant influence over the investee through our board representation or voting power. However, our influence is restricted by the GeneDx Holdings Shareholder Agreement, pursuant to which we have agreed to vote our shares of GeneDx Holdings Common Stock in accordance with the recommendation of GeneDx Holdings's board of directors for so long as we continue to hold at least 5% of the outstanding shares of GeneDx Holdings Common Stock. Other than through our sole board seat, we are unable to influence GeneDx Holdings's policy-making process. We hold one of nine seats on GeneDx Holdings board of directors, and our designee may continue to serve following the expiration of the lock-up period if the GeneDx Holdings stockholders elect him to continue serving on the board. We elected to account for our investment in GeneDx Holdings under the equity method fair value option and record gains and losses from changes in fair value in other income (expense), net in our Condensed Consolidated Statements of Operations For the three months ended March 31, 2023, we recognized $8.3 million in net income for fair value changes in our GeneDx Holdings investment. As of March 31, 2023, the aggregate value of our GeneDx Holdings investment based on the quoted market price of their respective shares of common stock and the number of shares held by us was $34.4 million.

Investments in Equity Securities

Our equity securities consist of investments in VBI Vaccines Inc. ("VBI") (1%), ChromaDex Corporation ("ChromaDex") (0.1%), Eloxx Pharmaceuticals, Inc. ("Eloxx") (1.5%), and CAMP4 Therapeutics Corporation ("CAMP4") (2%) and HealthSnap, Inc. (7%). We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of these investments. Accordingly, we account for our investment in these entities as equity securities, and we record changes in the fair value of these investments in Other income (expense) each reporting period when they have readily determinable fair value. Equity securities without a readily determinable fair value are adjusted to fair value when there is an observable price change. Net gains and losses on our equity securities for the three months ended March 31, 2023 and 2022 were as follows:

	For the three months ended March 31	
(in thousands)	2023	2022
Equity Securities:		
Net gains and losses recognized during the period on equity securities	$ (105)	$ (1,162)
Unrealized net losses recognized during the period on equity securities still held at the reporting date	$ (105)	$ (1,162)

Sales of investments

Gains (losses) included in earnings from sales of our investments are recorded in Other income (expense), net in our Condensed Consolidated Statement of Operations. The cost of securities sold is based on the specific identification method.

Warrants and options

In addition to our equity method investments and equity securities, we hold options to purchase 47 thousand additional shares of BioCardia, all of which were vested as of March 31, 2023 and December 31, 2022, and 33 thousand and 0.7 million warrants to purchase additional shares of COCP and InCellDx Inc., respectively. We recorded the changes in the fair value of the options and warrants in Fair value changes of derivative instruments, net in our Condensed Consolidated Statement of Operations. We also recorded the fair value of the options and warrants in Investments, net in our Condensed Consolidated Balance Sheet. See further discussion of the Company's options and warrants in Note 9 and Note 10.

Investments in variable interest entities

We have determined that we hold variable interests in LeaderMed and Zebra Biologics, Inc. ("Zebra"). We made this determination as a result of our assessment that they do not have sufficient resources to carry out their principal activities without additional financial support.

In September 2021, we and LeaderMed, a pharmaceutical development company with operations based in Asia, formed a joint venture to develop, manufacture and commercialize two of OPKO's clinical stage, long-acting drug products in Greater China and eight other Asian territories. Under the terms of the agreements, we granted the joint venture exclusive rights to develop, manufacture and commercialize (a) OPK88003, an oxyntomodulin analog being developed for the treatment of obesity and diabetes, and (b) Factor VIIa-CTP, a novel long acting coagulation factor being developed to treat hemophilia, in exchange for 4,703 shares 47% ownership interest in the joint venture. In addition, we received an upfront payment of $1.0 million and will be reimbursed for clinical trial material and technical support we provide the joint venture.

In order to determine the primary beneficiary of the joint venture, we evaluated our investment and our related parties' investment, as well as our investment combined with the related parties' investment to identify if we had the power to direct the activities that most significantly impact the economic performance of the joint venture. Based on the capital structure, governing documents and overall business operations of the joint venture, we determined that, while a VIE, we do not have the power to direct the activities that most significantly impact the joint venture's economic performance and do not have an obligation to fund expected losses. We did determine that we can significantly influence control of the joint venture through our board representation and voting power. Therefore, we have the ability to exercise significant influence over the joint venture's operations and account for our investment in the joint venture under the equity method.

We own 1,260,000 shares of Zebra's Series A-2 Preferred Stock and 900,000 shares of Zebra restricted common stock (ownership 29% at March 31, 2023 and December 31, 2022). Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Dr. Richard Lerner, M.D., a former member of our Board of Directors, is a founder of Zebra and, along with Dr. Frost, serves as a member of Zebra's Board of Directors.

In order to determine the primary beneficiary of Zebra, we evaluated our investment and our related parties' investment, as well as our investment combined with the related parties' investment to identify if we had the power to direct the activities that most significantly impact the economic performance of Zebra. Based on the capital structure, governing documents and overall business operations of Zebra, we determined that, while a VIE, we do not have the power to direct the activities that most significantly impact Zebra's economic performance and have no obligation to fund expected losses. We determined, however, that we can significantly influence control of Zebra through our board representation and voting power. Therefore, we have the ability to exercise significant influence over Zebra's operations and account for our investment in Zebra under the equity method.

NOTE 7 DEBT

As of March 31, 2023 and December 31, 2022, our debt consisted of the following:

(In thousands)	March 31, 2023	December 31, 2022
2025 Notes	$ 142,375	$ 142,096
2023 Convertible Notes	68,953	68,275
2033 Senior Notes	—	3,050
JP Morgan Chase	10,942	18,080
Chilean and Spanish lines of credit	11,318	13,740
Current portion of notes payable	2,111	1,720
Long term portion of notes payable	8,944	9,290
Total	$ 244,643	$ 256,251
Balance sheet captions		
Current portion of convertible notes	$ —	$ 3,050
Long term portion of convertible notes	211,328	210,371
Current portion of lines of credit and notes payable	24,371	33,540
Long Term notes payable included in long-term liabilities	8,944	9,290
Total	$ 244,643	$ 256,251

In February 2019, we issued $200.0 million aggregate principal amount of Convertible Senior Notes due 2025 (the "2025 Notes") in an underwritten public offering. The 2025 Notes bear interest at a rate of 4.50% per year, payable semiannually in arrears on February 15 and August 15 of each year. The 2025 Notes mature on February 15, 2025, unless earlier repurchased, redeemed or converted.

Holders may convert their 2025 Notes into shares of Common Stock at their option at any time prior to the close of business on the business day immediately preceding November 15, 2024 only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ended March 31, 2019 (and only during such calendar quarter), if the last reported sale price of our Common Stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of 2025 Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our Common Stock and the conversion rate on each such trading day; (3) if we call any or all of the 2025 Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or (4) upon the occurrence of specified corporate events set forth in the indenture governing the 2025 Notes. On or after November 15, 2024, until the close of business on the business day immediately preceding the maturity date, holders of the 2025 Notes may convert their notes at any time, regardless of the foregoing conditions. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our Common Stock, or a combination of cash and shares of our Common Stock, at our election.

The initial and current conversion rate for the 2025 Notes is 236.7424 shares of Common Stock per $1,000 principal amount of 2025 Notes (equivalent to a conversion price of approximately $4.22 per share of Common Stock). The conversion rate for the 2025 Notes is subject to adjustment in certain events but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date of the 2025 Notes or if we deliver a notice of redemption, in certain circumstances the indenture governing the 2025 Notes requires an increase in the conversion rate of the 2025 Notes for a holder who elects to convert its notes in connection with such a corporate event or notice of redemption, as the case may be.

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”).

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 March 31, 2023 and December 31, 2022, 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 the calculation of basic and diluted earnings per share. See Note 4.

The following table sets forth information related to the 2025 Notes which is included in our Condensed Consolidated Balance Sheet as of March 31, 2023:

(In thousands)	2025 Senior Notes	Debt Issuance Cost	Total
Balance at December 31, 2022	$ 144,580	$ (2,484)	$ 142,096
Amortization of debt discount and debt issuance costs	—	279	279
Balance at March 31, 2023	$ 144,580	$ (2,205)	$ 142,375

In August 2020, the FASB issued ASU No. 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40).” ASU 2020-06 simplifies the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. The ASU is effective for public entities for fiscal years beginning after December 15, 2021, with early adoption permitted. As required, we adopted ASU 2020-06 on January 1, 2022 and used the modified retrospective approach for all convertible debt instruments at the beginning of the period of adoptions. Results for reporting periods beginning January 1, 2022 are presented under ASU 2020-06, while prior period amounts were not adjusted and continue to be reported in accordance with historic accounting guidance.

Under the modified approach, entities will apply the guidance to all financial instruments that are outstanding as of the beginning of the year of adoption with the cumulative effect recognized as an adjustment to the opening balance of retained earnings. ASU 2020-06 eliminates the cash conversion and beneficial conversion feature models in ASC 470-20 that require an issuer of certain convertible debt and preferred stock to separately account for embedded conversion features as a component of equity. The adoption of ASU 2020-06 at January 1, 2022 resulted in an increase of the Convertible notes of $21.6 million, a reduction of the Accumulated deficit of $17.5 million and a reduction of Additional paid-in capital of $39.1 million.

In February 2018, we issued a series of 5% Convertible Promissory Notes (the “2023 Convertible Notes”) in the aggregate principal amount of $55.0 million. The original maturity of the 2023 Convertible Notes was five years following the date of issuance. Each holder of a 2023 Convertible Note has 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 at a conversion price of $5.00 per share. We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon, pro rata among the holders, upon no fewer than 30 days, and no more than 60 days, notice to the holders. The 2023 Convertible Notes contain customary events of default and representations and warranties of OPKO.

Purchasers of the 2023 Convertible Notes included an affiliate of Dr. Phillip Frost, M.D., our Chairman and Chief Executive Officer, and Dr. Jane H. Hsiao, Ph.D., MBA, our Vice-Chairman and Chief Technical Officer.

On February 10, 2023, the Company amended the 2023 Convertible Notes to extend the maturity to January 31, 2025, and to reset the conversion price to the 10 day volume weighted average price immediately preceding the date of the amended note, plus a 25% conversion premium, or $1.66. In addition, under the terms of the 2023 Convertible Notes, interest will accrue from the most recent date to which interest has been paid or, if no interest has been paid, from the date of issuance, until the principal and accrued and unpaid interest, are paid in full. The remaining provisions of the original note are unchanged.

In January 2013, we issued an aggregate of $175.0 million of our 3.0% Senior Notes due 2033 (the "2033 Senior Notes") in a private placement exempt from registration under the Securities Act. The 2033 Senior Notes bore interest at the rate of 3.0% per year, payable semiannually on February 1 and August 1 of each year and matured on February 1, 2033, unless earlier repurchased, redeemed or converted.

From 2013 to 2016, holders of the 2033 Senior Notes converted $143.2 million in aggregate principal amount into an aggregate of 21,539,873 shares of Common Stock. On February 1, 2019, approximately $28.8 million aggregate principal amount of 2033 Senior Notes were tendered by holders pursuant to such holders' option to require us to repurchase the 2033 Senior Notes as set forth in the indenture, governing the 2033 Senior Notes, following which repurchase only $3.0 million aggregate principal amount of the 2033 Senior Notes remained outstanding.

During the first quarter of 2023, we paid approximately $3.0 million to purchase the remaining 2033 Senior Notes, which the holders thereof tendered to us in accordance with the indenture governing the 2033 Senior Notes.

In November 2015, BioReference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. ("CB"), as lender and administrative agent, as amended (the "Credit Agreement"). As amended, the Credit Agreement provides for a $75.0 million secured revolving credit facility and includes a $20.0 million sub-facility for swingline loans and a $20.0 million sub-facility for the issuance of letters of credit.

The Credit Agreement is guaranteed by all of BioReference's domestic subsidiaries and is also secured by substantially all assets of BioReference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in BioReference. Availability under the Credit Agreement is based on a borrowing base composed of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein. As of March 31, 2023, $16.2 million remained available for borrowing under the Credit Agreement. Principal under the Credit Agreement is due upon maturity on August 30, 2024.

At BioReference's option, borrowings under the Credit Agreement (other than swingline loans) bear interest at (i) the CB floating rate (defined as the higher of (a) the prime rate and (b) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) for an interest period of one month plus 2.50%) plus an applicable margin of 0.75% or (ii) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) plus an applicable margin of 1.75%. Swingline loans will bear interest at the CB floating rate plus the applicable margin. The Credit Agreement also calls for other customary 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 March 31, 2023 and December 31, 2022, $10.9 million and $18.1 million, 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 obligations under the Credit Agreement. Substantially all the assets of BioReference and its subsidiaries are restricted from sale, transfer, lease, disposal or distributions to the Company, subject to certain exceptions. As of March 31, 2023, BioReference and its subsidiaries had net assets of approximately $567.7 million, which included goodwill of $283.0 million and intangible assets of $182.9 million.

On April 29, 2022, the Credit Agreement was restated and amended to, among other things, (i) waive specified defaults under the Credit Agreement resulting from certain internal reorganization transactions that resulted in both BioReference and

our former subsidiary, GeneDx, changing their respective forms of organization from New Jersey corporations to Delaware limited liability companies, (ii) provide for the disposition of GeneDx pursuant to the transactions contemplated by the GeneDx Merger Agreement, (iii) amend certain reporting requirements under the Credit Agreement and (iv) provide that the borrowers under the Credit Agreement may effect certain restricted payments to the extent necessary for their parent entities to pay income tax in respect of income earned by the borrowers.

In addition to the Credit Agreement, we had line of credit agreements with thirteen other financial institutions as of March 31, 2023, and December 31, 2022, in the U.S., Chile and Spain. These lines of credit are used primarily as sources of working capital for inventory purchases.

The following table summarizes the amounts outstanding under the BioReference, Chilean and Spanish lines of credit:

(Dollars in thousands)			Balance Outstanding	
Lender	Interest rate on borrowings at March 31, 2023	Credit line capacity	March 31, 2023	December 31, 2022
JPMorgan Chase	5.50%	$ 75,000	$ 10,942	$ 18,080
Itau Bank	5.50%	1,900	2,028	2,378
Bank of Chile	6.60%	2,500	1,254	817
BICE Bank	5.50%	2,500	1,360	1,661
Scotiabank	5.00%	5,500	1,887	1,646
Santander Bank	5.50%	5,000	987	1,238
Security Bank	5.50%	1,400	530	755
Estado Bank	5.50%	4,000	463	1,621
BCI Bank	5.00%	2,500	998	2,100
Internacional Bank	5.50%	1,500	1,082	599
Consoorcio Bank	5.00%	2,000	729	925
Banco De Sabadell	1.75%	544	—	—
Santander Bank	2.15%	544	—	—
Total		$ 104,888	$ 22,260	$ 31,820

For both March 31, 2023 and December 31, 2022, the weighted average interest rate on our lines of credit was approximately 5.4%.

At March 31, 2023 and December 31, 2022, we had notes payable and other debt (excluding the 2033 Senior Notes, the 2023 Convertible Notes, the 2025 Notes, the Credit Agreement and amounts outstanding under lines of credit described above) as follows:

(In thousands)	March 31, 2023	December 31, 2022
Current portion of notes payable	$ 2,111	$ 1,720
Other long-term liabilities	8,944	9,290
Total	$ 11,055	$ 11,010

The notes and other debt mature at various dates ranging from 2023 through 2032, bearing variable interest rates from 0.7% up to 5.1%. The weighted average interest rate on the notes and other debt was 4.1% on March 31, 2023 and 3.5% on December 31, 2022. The notes are partially secured by our office space in Barcelona.

NOTE 8 ACCUMULATED OTHER COMPREHENSIVE LOSS

For the three months ended March 31, 2023, changes in Accumulated other comprehensive loss, net of tax, were as follows:

(In thousands)	Foreign currency translation
Balance at December 31, 2022	$ (43,323)
Other comprehensive income	5,712
Balance at March 31, 2023	$ (37,611)

NOTE 9 FAIR VALUE MEASUREMENTS

We record fair values at an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability. We utilize a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers are: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

As of March 31, 2023, we had equity securities and an equity method fair value option (refer to Note 6), forward foreign currency exchange contracts for inventory purchases (refer to Note 10) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics and OPKO Renal that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with BioCardia, we record the related BioCardia options at fair value as well as the warrants from COCP.

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

	Fair value measurements as of March 31, 2023			
(In thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$ 52,074	$ —	$ —	$ 52,074
Equity securities	543	—	—	543
Equity Method - FV option	34,414	—	—	34,414
Common stock options/warrants	—	26	—	26
Total assets	$ 87,031	$ 26	$ —	$ 87,057
Liabilities:				
Forward contracts	—	884	—	884
Contingent consideration	—	—	1,179	1,179
Total liabilities	$ —	$ 884	$ 1,179	$ 2,063

(In thousands)	Fair value measurements as of December 31, 2022			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$ 102,773	$ —	$ —	$ 102,773
Equity securities	$ 648	$ —	$ —	$ 648
Equity Method - fair value option	21,120	—	—	21,120
Common stock options/warrants	—	28	—	28
Total assets	$ 124,541	$ 28	$ —	$ 124,569
Liabilities:				
Forward contracts	—	1,123	—	1,123
Contingent consideration	—	—	1,036	1,036
Total liabilities	$ —	$ 1,123	$ 1,036	$ 2,159

The carrying amount and estimated fair value of our 2025 Notes, as well as the applicable fair value hierarchy tiers, are contained in the table below. The fair value of the 2025 Notes is determined using inputs other than quoted prices in active markets that are directly observable.

(In thousands)	March 31, 2023				
	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2025 Notes	$ 142,375	$ 130,122	$ —	$ 130,122	$ —

There have been no transfers between Level 1 and Level 2 and no transfers to or from Level 3 of the fair value hierarchy.

As of March 31, 2023 and December 31, 2022, the carrying value of our other financial instrument assets approximates their fair value due to their short-term nature or variable rate of interest.

The following table reconciles the beginning and ending balances of our Level 3 assets and liabilities as of March 31, 2023:

(In thousands)	March 31, 2023
	Contingent consideration
Balance at December 31, 2022	$ 1,036
Change in fair value:	
Included in results of operations	136
Foreign currency impact	7
Balance at March 31, 2023	$ 1,179

The estimated fair values of our financial instruments have been determined by using available market information and what we believe to be appropriate valuation methodologies. We use the following methods and assumptions in estimating fair value:

Contingent consideration – We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to, CURNA and OPKO Renal transactions. As of March 31, 2023, of the $1.2 million of contingent consideration, $0.1 million was recorded in Accrued expenses and $1.1 million of contingent consideration was recorded in Other long-term liabilities. As of December 31, 2022, $1.0 million of contingent consideration was recorded in accrued expenses and other long-term liabilities. As a result of our execution of the CAMP4 Agreement (as

defined in Note 14), we will have to pay a percentage of any payments received under the CAMP4 Agreement to the former CURNA stockholders.

NOTE 10 DERIVATIVE CONTRACTS

The following table summarizes the fair values and the presentation of our derivative financial instruments in the Condensed Consolidated Balance Sheets:

(In thousands)	Balance Sheet Component	March 31, 2023	December 31, 2022
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 26	$ 28
Forward contracts	Unrealized losses on forward contracts are recorded in Accrued expenses.	$ (884)	$ (1,123)

We enter into foreign currency forward exchange contracts with respect to the risk of exposure to exchange rate differences arising from inventory purchases on letters of credit. Under these forward contracts, for any rate above or below the fixed rate, we receive or pay the difference between the spot rate and the fixed rate for the given amount at the settlement date.

To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At March 31, 2023 and December 31, 2022, our derivative financial instruments did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize the changes in Fair value of derivative instruments, net in our Condensed Consolidated Statement of Operations. The following table summarizes the losses and gains recorded for the three and three months ended March 31, 2023 and 2022:

	Three months ended March 31,	
(In thousands)	2023	2022
Derivative loss:		
Common Stock options/warrants	$ (2)	$ (1)
Forward contracts	(1,057)	(131)
Total	$ (1,059)	$ (132)

NOTE 11 RELATED PARTY TRANSACTIONS

On April 29, 2022, upon consummation of the GeneDx Transaction, the Company entered into a Transition Services Agreement (the "Transition Services Agreement"), with GeneDx (now a wholly owned subsidiary of GeneDx Holdings), pursuant to which the Company agreed to provide, at cost, certain customary support services in respect of GeneDx's business through December 31, 2022, including human resources, information technology support, and finance and accounting. As of March 31, 2023, the Company had incurred aggregate expenses of $2.0 million for services rendered under the Transition Services Agreement. For the three months ended March 31, 2023, the company incurred expenses of $0.7 million for services rendered under the Transaction Services Agreement. As of March 31, 2023, the company has a receivable of $0.6 million payable to the Company by GeneDx in accordance with the terms of the Transition Services Agreement.

The Company owns approximately 9% of Pharmsynthez and Pharmsynthez is Xenetic's largest and controlling stockholder. Dr. Richard Lerner, a director of the Company until his death on December 2, 2021, was a co-inventor of Xenetic's technology and received 31,240 shares of Xenetic upon the closing of the Xenetic transactions described above. Adam Logal, our Senior Vice President and Chief Financial Officer, is a director of Xenetic.

We hold investments in Zebra (ownership 29%), Neovasc (0.5%), ChromaDex Corporation (0.1%), COCP (3%), NIMS (1%), Eloxx (1.5%), BioCardia (1%) and LeaderMed Health Group Limited (47%). These investments were considered related party transactions as a result of our executive management's ownership interests and/or board representation in these entities. We also hold an investment in GeneDx Holdings (Nasdaq: WGS) representing an 11.8% ownership interest as a result of our sale of GeneDx, Inc. and subsequent participation in an underwritten offering by GeneDx Holdings. Rick Pfenniger who sits on our Board also sits on the GeneDx Board as a result of the acquisition. See further discussion of our investments in Note 6.

We lease office space from Frost Real Estate Holdings, LLC ("Frost Holdings") in Miami, Florida, where our principal executive offices are located. Effective August 1, 2019, we entered into an amendment to our lease agreement with Frost

Holdings. The lease, as amended, is for approximately 29,500 square feet of space. The lease provides for payments of approximately $89 thousand per month in the first year increasing annually to $101 thousand per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking.

Dr. Elias Zerhouni, our Vice Chairman and President, sits on the board of directors of Danaher Corporation ("Danaher"). Our subsidiary, BioReference, routinely procures products and services from several subsidiaries of Danaher, including Beckman Coulter, Integrated DNA Technologies Inc., and Leica Microsystems Inc., to which BioReference has paid $925.8 thousand, $15.4 thousand, and $94.3 thousand, respectively, during three months ended March 31, 2023 .

BioReference purchases and uses certain products acquired from InCellDx, a company in which we hold a 29% minority interest.

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost for out-of-pocket operating costs for the use of the airplane by Dr. Frost or Company executives for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive. For the three months ended March 31, 2023 and 2022, we reimbursed approximately $29.3 thousand and $31.0 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

NOTE 12 COMMITMENTS AND CONTINGENCIES

In February 2023, the Office of the Attorney General for the State of Texas ("TX OAG") informed BioReference that it believes that, from 2005 to the present, BioReference may have violated the Texas Medicaid Fraud Prevention Act with respect to claims it presented to Texas Medicaid for reimbursement. BioReference has not determined whether there is any merit to the TX OAG 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 materially and adversely affect our business, financial condition, results of operations, and cash flows.

On December 29, 2022, the Israel Tax Authority (the "ITA") issued an assessment against our subsidiary, OPKO Biologics in the amount of approximately $246 million (including interest) related to uncertain tax positions involving income recognition in connection with an examination of foreign tax returns for the 2014 through 2020 tax years. We recognize that local tax law is inherently complex and the local taxing authorities may not agree with certain tax positions taken.We are appealing this assessment, as we believe, other than for uncertain tax positions for which we have reserved, the issues are without technical merit. We intend to exhaust all judicial remedies necessary to resolve the matter, as necessary, which could be a lengthy process. There can be no assurance that this matter will be resolved in our favor, and an adverse outcome, or any future tax examinations involving similar assertions, could have a material adverse effect on our financial condition, results of operations and cash flows.

In connection with our acquisitions of CURNA, OPKO Diagnostics and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of March 31, 2023, we recorded $1.2 million as contingent consideration, with $0.1 million recorded in Accrued expenses and $1.1 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 5.

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 GeneDx Holdings 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. 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 action. The Company generally has cooperated, and intends to continue to cooperate, with appropriate regulatory authorities as and when investigations, audits and inquiries arise.

We are a party to other litigation in the ordinary course of business. While we cannot predict the ultimate outcome of legal matters, we accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. It's reasonably possible the ultimate liability could exceed amounts currently estimated and we review established accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. Because of the high degree of judgment involved in establishing loss estimates, the ultimate outcome of such matters will differ from our estimates and such differences may be material to our business, financial condition, results of operations, and cash flows.

At March 31, 2023, we were committed to make future purchases for inventory and other items in 2023 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating approximately $52.8 million.

NOTE 13 REVENUE RECOGNITION

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

Revenue from services

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

The following are descriptions of our payors for laboratory services:

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

of our contractual arrangements. 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 we will continue to do so in the future. If a third-party payor denies payment for testing or recoups money from us in a later period, reimbursement for our testing could decline.

As an integral part of our billing compliance program, we periodically assess our billing and coding practices, respond to payor audits on a routine basis, and investigate reported failures or suspected failures to comply with federal and state healthcare reimbursement requirements, as well as overpayment claims which may arise from time to time without fault on the part of the Company. We may have an obligation to reimburse Medicare, Medicaid, and third-party payors for overpayments regardless of fault. We have periodically identified and reported overpayments, reimbursed payors for overpayments and taken appropriate corrective action.

Settlements with third-party payors for retroactive adjustments due to audits, reviews or investigations are also considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews, and investigations. As of March 31, 2023 and December 31, 2022, we had liabilities of approximately $2.2 million and $1.8 million, respectively, within Accrued expenses and Other long-term liabilities related to reimbursements for payor overpayments.

The composition of revenue from services by payor for the three months ended March 31, 2023 and 2022 was as follows:

(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:

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2022	$ 1,532	$ 5,063	$ 1,683	$ 8,278
Provision related to current period sales	3,306	4,045	286	7,637
Credits or payments made	(3,264)	(3,968)	(293)	(7,525)
Balance at March 31, 2023	$ 1,574	$ 5,140	$ 1,676	$ 8,390
Total gross *Rayaldee* sales				$ 14,281
Provision for *Rayaldee* sales allowances and accruals as a percentage of gross *Rayaldee* sales				53%

(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	3,215	4,869	269	8,353
Credits or payments made	(3,641)	(5,086)	(575)	(9,302)
Balance at March 31, 2022	$ 1,588	$ 5,282	$ 2,333	$ 9,203
Total gross *Rayaldee* sales				$ 13,479
Provision for *Rayaldee* sales allowances and accruals as a percentage of gross *Rayaldee* sales				62%

Taxes collected from customers related to revenues from services and revenues from products are excluded from revenues.

Revenue from intellectual property and other

We recognize revenues from the transfer of intellectual property generated through license, development, collaboration and/or commercialization agreements. The terms of these agreements typically include payment to us for one or more of the following: non-refundable, up-front license fees; development and commercialization milestone payments; funding of research and/or development activities; and royalties on sales of licensed products. Revenue is recognized upon satisfaction of a performance obligation by transferring control of a good or service to the customer.

For research, development and/or commercialization agreements that result in revenues, we identify all material performance obligations, which may include a license to intellectual property and know-how, and research and development activities. In order to determine the transaction price, in addition to any upfront payment, we estimate the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. We constrain (reduce) our estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur throughout the life of the contract. When determining if variable consideration should be constrained, we consider whether there are factors outside of our control that could result in a significant reversal of revenue. In making these assessments, we consider the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

Upfront License Fees: If a license to our intellectual property is determined to be functional intellectual property distinct from the other performance obligations identified in the arrangement, we recognize revenue from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we apply an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments: Depending on facts and circumstances, we may conclude that it is appropriate to include the milestone in the estimated transaction price or that it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period that we conclude that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. We may record revenues from certain milestones in a reporting period before the milestone is achieved if we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We record a corresponding contract asset when this conclusion is reached. Milestone payments that have been fully constrained are not included in the transaction price to date. These milestones remain fully constrained until we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We re-evaluate the probability of achievement of such development milestones and any related constraint each reporting period. We adjust our estimate of the overall transaction price, including the amount of revenue recorded, if necessary.

Research and Development Activities: If we are entitled to reimbursement from our customers for specified research and development expenses, we account for them as separate performance obligations if distinct. We also determine whether the

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 STRATEGIC ALLIANCES

Merck

On March 8, 2023, ModeX, the Company (with respect to certain sections), and Merck Sharp & Dohme LLC ("Merck") entered into a License and Research Collaboration Agreement (the "Merck Agreement") pursuant to which ModeX granted to Merck a license to certain patent rights and know-how in connection with the development of ModeX's preclinical nanoparticle vaccine candidate targeting the Epstein Barr Virus.

Under the terms of the Merck Agreement, ModeX granted to Merck an exclusive, sublicensable, royalty-bearing license to certain intellectual property to conduct research under a research program to be established by the parties and to develop, manufacture, use and commercialize (i) a multivalent or monovalent vaccine assembled using the our platform for Epstein-Barr Virus ("Vaccine"), and (ii) any pharmaceutical or biological preparation in final form containing a Vaccine for sale or for administration to human patients in a clinical trial for all uses ("Product"). We received an initial payment of $50.0 million and are eligible to receive up to an additional $872.5 million upon the achievement of certain commercial and development milestones under several indications. We are also eligible to receive tiered royalty payments ranging from high single digits to low double digits upon achievement of certain sales targets of the Product. Certain of the rights subject to the license provided by us under the Merck Agreement were obtained by us from Sanofi pursuant to that certain License Agreement entered into as of July 1, 2021 ("Sanofi In-License Agreement") between us and Sanofi, a French corporation ("Sanofi"), and a portion of the upfront payment, milestones and royalties received by us under the Merck Agreement may be payable to Sanofi under the terms

of the Sanofi In-License Agreement. As a result of such obligations under the Sanofi In-License Agreement, we recorded $12.5 million in Accrued expenses in the accompanying Condensed Consolidated Balance Sheets.

As part of the strategic collaboration, ModeX and Merck have agreed to establish a program for research and other development activities related to the development of a Vaccine or Product undertaken by the parties pursuant to a research plan. The parties will also establish a joint steering committee to facilitate the research program.

The Merck Agreement will remain in effect until one or more Products receive marketing authorization, and, thereafter, until the expiration of all royalty obligations unless earlier terminated as permitted under the Merck Agreement. In addition to termination rights for material breach and bankruptcy, Merck is permitted to terminate the Agreement in its entirety without cause after a specified notice period. If Merck terminates the Merck Agreement for convenience or by us for Merck's uncured material breach, we may elect to receive a reversion license such that we can continue its work with Vaccines and Products which have not been terminated due to a material safety issue.

LeaderMed

On September 14, 2021, we and LeaderMed announced the formation of a joint venture to develop, manufacture and commercialize two of OPKO's clinical stage, long-acting drug products in Greater China and eight other Asian territories.

Under the terms of the agreements, we have granted the joint venture exclusive rights to develop, manufacture and commercialize (a) OPK88003, an oxyntomodulin analog being developed for the treatment of obesity and diabetes, and (b) Factor VIIa-CTP, a novel long-acting coagulation factor being developed to treat hemophilia, in exchange for a 47% ownership interest in the joint venture. In addition, during 2021 we received an upfront payment of $1 million and will be reimbursed for clinical trial material and technical support we provide the joint venture.

LeaderMed has agreed to be responsible for funding the joint venture's operations, development and commercialization efforts and, together with its syndicate partners, initially invested $11 million in exchange for a 53% ownership interest. We retain full rights to oxyntomodulin and Factor VIIa-CTP in all other geographies.

CAMP4 Therapeutics

On July 6, 2021, we entered into an exclusive license agreement (the "CAMP4 Agreement") with CAMP4, pursuant to which we granted to CAMP4 an exclusive license to develop, manufacture, commercialize or improve therapeutics utilizing the AntagoNAT technology, an oligonucleotide platform developed under OPKO CURNA, which includes the molecule for the treatment of Dravet syndrome, together with any derivative or modification thereof (the "Licensed Compound") and any pharmaceutical product that comprises or contains the Licensed Compound, alone or in combination with one or more other active ingredients ("Licensed Product"), worldwide. The CAMP4 Agreement grant covers human pharmaceutical, prophylactic, and therapeutic and certain diagnostic uses.

We received an initial upfront payment of $1.5 million and 3,373,008 shares of CAMP4's Series A Prime Preferred Stock ("Preferred Stock"), which equates to approximately 9% of the outstanding shares of CAMP4, and we are eligible to receive up to $3.5 million in development milestone payments for Dravet syndrome products, and $4 million for non-Dravet syndrome products, as well as sales milestones of up to $90 million for Dravet syndrome products and up to $90 million for non-Dravet syndrome products. We may also receive double digit royalty payments on the net sales of royalty bearing products, subject to adjustment. In addition, upon achievement of certain development milestones, we will be eligible to receive equity consideration of up to 5,782,299 shares of Preferred Stock in connection with Dravet syndrome products and up to 1,082,248 shares of Preferred Stock in connection with non-Dravet syndrome products. In connection with our acquisition of CURNA, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result of our execution of the CAMP4 Agreement, we will have to pay a percentage of any payments received under the CAMP4 Agreement to the former CURNA stockholders.

Unless earlier terminated, the CAMP4 Agreement will remain in effect on a Licensed Product-by-Licensed Product and country by-country basis until such time as the royalty term expires for a Licensed Product in a country, and expires in its entirety upon the expiration of the royalty term for the last Licensed Product in the last country. CAMP4's royalty obligations expire on the later of (i) the expiration, invalidation or abandonment date of the last patent right in connection with the royalty bearing product, or (ii) ten (10) years after a royalty bearing product's first commercial sale in a country. In addition to termination rights for material breach and bankruptcy, CAMP4 is permitted to terminate the CAMP4 Agreement after a specified notice period.

NICOYA Macau Limited

On June 18, 2021, EirGen, our wholly owned subsidiary, and NICOYA Macau Limited ("Nicoya"), a Macau corporation and an affiliate of NICOYA Therapeutics, entered into a Development and License Agreement (the "Nicoya Agreement") granting Nicoya the exclusive rights for the development and commercialization of extended release calcifediol (the "Nicoya Product") in Greater China, which includes mainland China, Hong Kong, Macau, and Taiwan (collectively, the "Nicoya Territory"). Extended release calcifediol is marketed in the U.S. by OPKO under the tradename Rayaldee. The license grant to Nicoya covers the therapeutic and preventative use of the Nicoya Product for SHPT in non-dialysis and hemodialysis chronic kidney disease patients (the "Nicoya Field").

EirGen received an initial upfront payment of $5 million and was eligible to receive an additional $5 million tied to the first anniversary of the effective date of the Nicoya Agreement, as amended, of which EirGen has received $2.5 million plus accrued interest for the delayed payment. Furthermore, EirGen received the additional $2.5 million upon Nicoya's submission of an investigational new drug (IND) application to the Center for Drug Evaluation (CDE) of China in March 2023. EirGen is also eligible to receive up to an additional aggregate amount of $115 million upon the achievement of certain development, regulatory and sales-based milestones by Nicoya for the Nicoya Product in the Nicoya Territory. EirGen is eligible to receive tiered, double digit royalty payments at rates in the low double digits on net product sales within the Nicoya Territory and in the Nicoya Field.

Nicoya will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for the Nicoya Product in the Nicoya Territory and for all commercial activities pertaining to the Nicoya Product in the Nicoya Territory.

Unless earlier terminated, the Nicoya Agreement will remain in effect until such time as all royalty payment terms and extended payment terms have expired, and Nicoya shall have no further payment obligations to EirGen under the terms of the Nicoya Agreement. Nicoya's royalty obligations expire on the later of (i) expiration of the last to expire valid patent claim covering the Nicoya Product sold in the Nicoya Territory, (ii) expiration of all regulatory and data exclusivity applicable to the Nicoya Product in the Nicoya Territory, and (iii) on a product-by-product basis, ten (10) years after such Nicoya Product's first commercial sale in the Nicoya Territory. In addition to termination rights for material breach and bankruptcy, Nicoya is permitted to terminate the Nicoya Agreement after a specified notice period.

CSL Vifor

In May 2016, EirGen and Vifor Fresenius Medical Care Renal Pharma Ltd. ("Vifor") entered into a Development and License Agreement (the "Vifor Agreement") for the development and commercialization of *Rayaldee* worldwide, except for (i) the United States and Canada, (ii) any country in Central America or South America (including Mexico), (iii) Russia, (iv) China, (v) South Korea, (vi) Ukraine, (vii) Belorussia, (viii) Azerbaijan, (ix) Kazakhstan, (x) Taiwan (xi) the Middle East, and (xii) all countries of Africa (the "Vifor Territory"), as amended. The license to Vifor potentially covers all therapeutic and prophylactic uses of the Product in human patients (the "Vifor Field"), provided that initially the license is for the use of the Product for the treatment or prevention of SHPT related to patients with CKD and vitamin D insufficiency/deficiency (the "Vifor Initial Indication").

In January 2023, the price approval for *Rayaldee* was granted by the German Association of Statutory Health Insurance funds (GKV-SV), which triggered a milestone payment of $7.0 million for the three months ended March 31, 2023. For the three months ended March 31, 2022, we recognized a milestone payment of $3.0 million in revenue from transfer of intellectual property and other for the first sale of *Rayaldee* in Europe.

Effective May 23, 2021, we entered into an amendment to the Vifor Agreement pursuant to which the parties thereto agreed to include Japan as part of the Vifor Territory.

Effective May 5, 2020, we entered into an amendment to the Vifor Agreement pursuant to which the parties agreed to exclude Mexico, South Korea, the Middle East and all of the countries of Africa from the Vifor Territory. In addition, the parties agreed to certain amendments to the milestone structure and to reduce minimum royalties payable. As revised, the Company has received a $3 million payment triggered by the first marketing approval of *Rayaldee* in Europe, $7.0 million payment triggered by the Germany price approval by the local sick fund association, and is eligible to receive up to an additional $10 million in regulatory milestones and $207 million in milestone payments tied to launch, pricing and sales of *Rayaldee*, and tiered, double-digit royalties.

We plan to share responsibility with Vifor for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. EirGen will lead the manufacturing activities within and outside the Vifor Territory and the commercialization activities outside the Vifor Territory and outside the Vifor Field in the Vifor Territory and Vifor will lead the commercialization activities in the Vifor Territory and the Vifor Field. For the initial development plan, the companies have agreed to certain cost sharing arrangements. Vifor will be responsible for all other

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 gestational age (the "Pfizer Transaction").

In early 2022, the European Commission and Ministry of Health, Labour and Welfare in Japan approved the next-generation long-acting recombinant human growth hormone NGENLA (Somatrogon), a once-weekly injection to treat pediatric growth hormone deficiency, and we received pricing approvals in Germany and Japan. With the achievement of these milestones, we received $85.0 million in milestone payments in 2022. Further, Canada and Australia approved NGENLA in 2021.

In January 2022, the FDA issued a Complete Response Letter for the BLA for Somatrogon (hGH-CTP). Pfizer and OPKO are evaluating the FDA's comments and will work with the agency to determine the best path forward for Somatrogon (hGH-CTP) in the United States.

In May 2020, we entered into an Amended and Restated Development and Commercialization License Agreement (the "Restated Pfizer Agreement") with Pfizer, effective January 1, 2020, pursuant to which the parties agreed, among other things, to share all costs for Manufacturing Activities, as defined in the Restated Pfizer Agreement, for developing a licensed product for the three indications included in the Restated Pfizer Agreement.

On October 21, 2019, we and Pfizer announced that the global phase 3 trial evaluating Somatrogon dosed once-weekly in prepubertal children with GHD met its primary endpoint of non-inferiority to daily Genotropin® (somatropin) for injection, as measured by annual height velocity at 12 months.

Under the terms of the Pfizer Transaction, as restated, we received non-refundable and non-creditable upfront payments of $295.0 million and are eligible to receive up to an additional $275.0 million upon the achievement of certain regulatory milestones, $85 million of which we received during the second quarter of 2022. Pfizer received the exclusive license to commercialize Somatrogon worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of Somatrogon for adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of Somatrogon for pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both Somatrogon and Pfizer's Genotropin® (somatropin).

The agreement with Pfizer will remain in effect until the last sale of the licensed product, unless earlier terminated as permitted under the Pfizer Agreement. In addition to termination rights for material breach and bankruptcy, Pfizer is permitted to terminate the Pfizer Agreement in its entirety, or with respect to one or more world regions, without cause after a specified notice period. If the Pfizer Agreement is terminated by us for Pfizer's uncured material breach, or by Pfizer without cause, provision has been made for transition of product and product responsibilities to us for the terminated regions, as well as continued supply of product by Pfizer or transfer of supply to us in order to support the terminated regions.

We recognized the non-refundable $295.0 million upfront payments as revenue as the research and development services

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 the obligations are based on future development of the licensed products.

NOTE 15 SEGMENTS

We manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of our pharmaceutical operations in Chile, Mexico, Ireland, Israel and Spain, *Rayaldee* product sales and our pharmaceutical research and development. The diagnostics segment primarily consists of our clinical and genomics laboratory operations through BioReference and our point-of-care operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

Information regarding our operations and assets for our operating segments and the unallocated corporate operations as well as geographic information are as follows:

(In thousands)	For the three months ended March 31, 2023	2022
Revenue from services:		
Pharmaceutical	$ —	$ —
Diagnostics	132,368	286,599
Corporate	—	—
	$ 132,368	$ 286,599
Revenue from products:		
Pharmaceutical	$ 40,383	$ 36,658
Diagnostics	—	—
Corporate	—	—
	$ 40,383	$ 36,658
Revenue from transfer of intellectual property and other:		
Pharmaceutical	$ 64,826	$ 5,962
Diagnostics	—	—
Corporate	—	—
	$ 64,826	$ 5,962
Operating income (loss):		
Pharmaceutical	$ 18,955	$ (18,108)
Diagnostics	(40,007)	(43,548)
Corporate	(9,542)	(10,768)
	$ (30,594)	$ (72,424)
Depreciation and amortization:		
Pharmaceutical	$ 17,760	$ 15,402
Diagnostics	8,686	12,412
Corporate	—	—
	$ 26,446	$ 27,814
Loss from investment in investees:		
Pharmaceutical	$ (37)	$ (49)
Diagnostics	—	—
Corporate	—	—
	$ (37)	$ (49)
Revenues:		
United States	$ 189,085	$ 291,808
Ireland	15,846	8,462
Chile	15,541	16,339
Spain	6,110	7,109
Israel	4,594	1,558
Mexico	5,826	3,750
Other	575	193
	$ 237,577	$ 329,219

(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	283,025	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.

NOTE 16 LEASES

We have operating leases for office space, laboratory operations, research and development facilities, manufacturing locations, warehouses and certain equipment. We determine if a contract contains a lease at inception or modification of a contract. Our leases generally do not provide an implicit interest rate, and we therefore use our incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate we would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of the lease within a particular currency environment. We used the incremental borrowing rates as of January 1, 2019 for operating leases that commenced prior to that date. Many of our leases contain rental escalation, renewal options and/or termination options that are factored into our determination of lease payments as appropriate. Variable lease payment amounts that cannot be determined at the commencement of the lease are not included in the right-to-use assets or liabilities.

We elected the use of permitted practical expedients of not recording leases on our Condensed Consolidated Balance Sheet when the leases have terms of 12 months or less, and we elected not to separate nonlease components from lease components and instead account for each separate lease component and the nonlease components associated with that lease component as a single lease component.

The following table presents the lease balances within the Condensed Consolidated Balance Sheet as of March 31, 2023 and December 31, 2022:

(in thousands)	Classification on the Balance Sheet	March 31, 2023	December 31, 2022
Assets			
Operating lease assets	Operating lease right-of-use assets	$ 36,832	$ 38,725
Finance lease assets	Property, plant and equipment, net	10,858	9,898
Liabilities			
Current			
Operating lease liabilities	Current maturities of operating leases	11,490	11,628
Accrued expenses	Current maturities of finance leases	2,968	2,809
Long-term			
Operating lease liabilities	Operating lease liabilities	26,462	27,963
Other long-term liabilities	Finance lease liabilities	$ 7,890	$ 7,089
Weighted average remaining lease term			
Operating leases		6.1 years	6.0 years
Finance leases		6.6 years	6.5 years
Weighted average discount rate			
Operating leases		4.5 %	4.4 %
Finance leases		4.3 %	3.8 %

The following table reconciles the undiscounted future minimum lease payments (displayed by year and in the aggregate) under noncancelable operating leases with terms of more than one year to the total operating lease liabilities recognized on our Condensed Consolidated Balance Sheet as of March 31, 2023:

(in thousands)	Operating	Finance
April 1, 2023 through December 31, 2023	$ 9,286	$ 2,482
2024	8,464	2,724
2025	5,295	2,062
2026	4,030	1,402
2027	3,858	587
Thereafter	11,910	1,990
Total undiscounted future minimum lease payments	42,843	11,247
Less: Difference between lease payments and discounted lease liabilities	4,891	389
Total lease liabilities	$ 37,952	$ 10,858

Expense under operating leases and finance leases was $4.1 million and $0.7 million, respectively, for the three months ended March 31, 2023, which includes $0.6 million of variable lease costs. Expense under operating leases and finance leases was $4.6 million and $0.7 million, respectively, for the three months ended March 31, 2022, which includes $0.4 million of variable lease costs. Operating lease costs and finance lease costs are included within Operating loss in the Condensed Consolidated Statement of Operations. Short-term lease costs were not material.

Supplemental cash flow information is as follows:

(in thousands)	For the three months ended March 31,	
	2023	2022
Operating cash out flows from operating leases	$ 3,872	$ 4,288
Operating cash out flows from finance leases	108	33
Financing cash out flows from finance leases	656	498
Total	$ 4,636	$ 4,819

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

OVERVIEW

You should read this discussion together with the unaudited Condensed Consolidated Financial Statements, related notes, and other financial information included elsewhere in this Quarterly Report on Form 10-Q together with our audited consolidated financial statements, related notes, and other information contained in our Annual Report on Form 10-K for the year ended December 31, 2022 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part I, Item 1A of the Form 10-K and as described from time to time in our other filings with the Securities and Exchange Commission. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference 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 is partnered with Pfizer Inc. ("Pfizer"). 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 3 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 Ireland, Chile, Spain, Mexico, and the U.S.,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. In addition, we have a development and commercial supply pharmaceutical company and a global supply chain operation and holding company in Ireland. We own an 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.

RESULTS OF OPERATIONS

Impact of COVID-19

We continue to be a part of the coordinated public and private sector response to the COVID-19 pandemic. There continues to be a high level of uncertainty relating to the pandemic's continuing evolution, including how governments and consumers will react to new developments, and whether the pandemic will have a longer-term effect on the healthcare industry and patient habits. BioReference has been providing COVID-19 solutions, including diagnostic molecular testing and serology antibody testing, to meet the testing needs of its customers, including physicians, health systems, long-term care facilities, governments, schools, employers, professional sports teams and entertainment venues, as well as the general public through relationships with retail pharmacy chains.

Throughout the pandemic, we have managed our company-wide lab operations specimen acquisition, logistics, procurement, customer service, and initiatives to manage our cost structure to match the ever changing COVID-19 testing volumes and to identify and capitalize on efficiencies in our core clinical lines of business. While BioReference benefited from significant COVID-19 testing volumes in 2020 and 2021, demand declined in 2022 and continued to decline during the first quarter of 2023.

Revenue from services for the three months ended March 31, 2023, decreased by $154.2 million as compared to the same period in 2022 due to lower COVID-19 testing volumes. Excluding COVID-19 test volumes, for the three months ended March 31, 2023, routine clinical test volumes increased 6.8% as compared to volumes for the three months ended March 31, 2022.

Foreign Currency Exchange Rates

Approximately 18.5% of revenue for the three months ended March 31, 2023, and approximately 10.9% of revenue for the three months ended March 31, 2022, were denominated in currencies other than the U.S. Dollar (USD). Our financial statements are reported in USD and, accordingly, fluctuations in exchange rates will affect the translation of revenues and expenses denominated in foreign currencies into USD for purposes of reporting the consolidated financial results. In the first quarter of 2023 and the year ended December 31, 2022, the most significant currency exchange rate exposures were to the Euro and Chilean Peso. Gross accumulated currency translation adjustments recorded as a separate component of shareholders' equity were $34.2 million and $39.9 million at March 31, 2023, and December 2022, respectively.

We are subject to foreign currency transaction risk for fluctuations in exchange rates during the period of time between the consummation and cash settlement of transactions. We limit foreign currency transaction risk through hedge transactions with foreign currency forward contracts. Under these forward contracts, for any rate above or below the fixed rate, we receive or pay the difference between the spot rate and the fixed rate for the given amount at the settlement date. At March 31, 2023, we had 177 open foreign exchange forward contracts relating to inventory purchases on letters of credit with various amounts maturing monthly through April 2023 with a notional value totaling approximately $10.4 million. At December 31, 2022, we had 194 open foreign exchange forward contracts relating to inventory purchases on letters of credit with various amounts maturing monthly through January 2023 with a notional value totaling approximately $11.9 million.

FOR THE THREE MONTHS ENDED MARCH 31, 2023 AND 2022

Our consolidated income (loss) from operations for the three months ended March 31, 2023 and 2022 was as follows:

(In thousands)	For the three months ended March 31, 2023	2022	Change	% Change
Revenues:				
Revenue from services	$ 132,368	$ 286,599	$ (154,231)	(54)%
Revenue from products	40,383	36,658	3,725	10 %
Revenue from transfer of intellectual property and other	64,826	5,962	58,864	987 %
Total revenues	237,577	329,219	(91,642)	(28)%
Costs and expenses:				
Cost of revenue	138,314	243,875	(105,561)	(43)%
Selling, general and administrative	75,642	117,537	(41,895)	(36)%
Research and development	32,605	18,312	14,293	78 %
Contingent Consideration	136	(106)	242	228 %
Amortization of intangible assets	21,474	22,025	(551)	(3)%
Total costs and expenses	268,171	401,643	(133,472)	(33)%
Loss from operations	(30,594)	(72,424)	41,830	58 %

Diagnostics

(In thousands)	For the three months ended March 31, 2023	2022	Change	% Change
Revenues				
Revenue from services	$ 132,368	$ 286,599	$ (154,231)	(54)%
Total revenues	132,368	286,599	(154,231)	(54)%
Costs and expenses:				
Cost of revenue	114,061	221,206	(107,145)	(48)%
Selling, general and administrative	52,576	94,957	(42,381)	(45)%
Research and development	689	6,222	(5,533)	(89)%
Amortization of intangible assets	5,049	7,762	(2,713)	(35)%
Total costs and expenses	172,375	330,147	(157,772)	(48)%
Loss from operations	(40,007)	(43,548)	3,541	8 %

Revenue. Revenue from services for the three months ended March 31, 2023, decreased by approximately $154.2 million compared to the three months ended March 31, 2022. The decrease in revenue for the three months ended March 31, 2023, reflects lower demand for COVID-19 testing and lower COVID-19 reimbursement of $126.8 million and $1.4 million, respectively. BioReference performed 68 thousand molecular tests for COVID-19 during the three months ended March 31, 2023, representing 4.8% of total volume for that period. In comparison, the three months ended March 31, 2022, included 1,981 thousand molecular tests for COVID-19 and 126 thousand serology antibody tests, representing 46.9% of total volume for the 2022 period. The reduction in reimbursement reflected an increase in utilization of antigen point of care diagnostic tests and a change in the mix of customers, which have varying contract prices depending on the level of services we provide.

Furthermore, clinical test reimbursement decreased by $6.9 million due to the mix of testing ordered offset by an increase in clinical test volume of $17.0 million. Moreover, revenues decreased by $36.1 million as a result of the GeneDx Transaction that closed in April 2022.

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. 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.

The composition of revenue from services by payor for the three months ended March 31, 2023 and 2022 was as follows:

	Three months ended March 31,	
(In thousands)	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

Client payors include cities, states and companies for which BioReference provides COVID-19 testing services.

Cost of revenue. Cost of revenue for the three months ended March 31, 2023 decreased $107.1 million compared to the three months ended March 31, 2022. Cost of revenue decreased primarily due to a decline in the volume of COVID-19 tests performed during the three months ended March 31, 2023, compared to 2022. Cost of revenue for the three months ended March 31, 2023, also decreased due to changes in the test mix during the period. In addition, cost of revenue decreased by $26.0 million as a result of the GeneDx Transaction, which closed in April 2022.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended March 31, 2023, and 2022 were $52.6 million and $95.0 million, respectively. Selling, general and administrative expenses in our diagnostics segment decreased primarily due to our sale of GeneDx. Furthermore, BioReference has implemented and continues to implement significant cost-reduction initiatives as it strives to return to profitability following the buildup and then decline of COVID related testing.

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

Research and Development Expenses	Three months ended March 31,	
	2023	2022
External expenses:		
Research and development employee-related expenses	372	4,926
Other internal research and development expenses	317	1,296
Total research and development expenses	$ 689	$ 6,222

The decrease in research and development expenses for the three months ended March 31, 2023, was primarily related to the development of more efficient clinical testing services at BioReference and as a result of the GeneDx Transaction.

Amortization of intangible assets. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets was $5.0 million and $7.8 million, respectively, for the three months ended March 31, 2023 and 2022. Amortization expense declined during the three months ending March 31, 2023, due to the GeneDx Transaction in April 2022.

Pharmaceuticals

(In thousands)	For the three months ended March 31, 2023	2022	Change	% Change
Revenues:				
Revenue from products	$ 40,383	$ 36,658	$ 3,725	10 %
Revenue from transfer of intellectual property and other	64,826	5,962	58,864	987 %
Total revenues	105,209	42,620	62,589	147 %
Costs and expenses:				
Cost of revenue	24,253	22,669	1,584	7 %
Selling, general and administrative	13,562	11,611	1,951	17 %
Research and development	31,878	12,291	19,587	159 %
Contingent Consideration	136	(106)	242	228 %
Amortization of intangible assets	16,425	14,263	2,162	15 %
Total costs and expenses	86,254	60,728	25,526	42 %
Income (loss) from operations	18,955	(18,108)	37,063	205 %

Revenue. Revenue from products for the three months ended March 31, 2023 and 2022 was $40.4 million and $36.7 million, respectively. The increase in revenue from products for the three months ended March 31, 2023, compared to the three months ended March 31, 2022, was driven by an increase in sales in our international operating companies and an increase in sales of *Rayaldee*. Revenue from sales of *Rayaldee* for the three months ended March 31, 2023, and 2022 was $6.6 million and $5.1 million, respectively. Revenue from transfer of intellectual property and other for the three months ended March 31, 2023, primarily reflects an upfront payment of $50.0 million from Merck Sharp & Dohme LLC (“Merck”) related to the Epstein-Barr Virus agreement and a $7.0 million payment from Vifor under the Vifor Agreement (each as defined in Note 14 to our condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q) triggered by the German price approval related to *Rayaldee.* Furthermore, we recorded $2.5 million from Nicoya due to Nicoya’s submission of the investigational new drug application to China's Center for Drug Evaluation pursuant to the Nicoya Agreement (as defined in Note 14 to our condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q). 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, related to the Pfizer Transaction (as defined in Note 14 to our condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q). 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 under the Vifor Agreement.

Cost of revenue. Cost of revenue for the three months ended March 31, 2023 increased $1.6 million compared to the three months ended March 31, 2022, primarily due to changes in product mix during the period and unfavorable foreign exchange fluctuations at our international operating companies driven by higher inventory costs compared to the prior year.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended March 31, 2023 and 2022 were $13.6 million and $11.6 million, respectively. The increase in selling, general and administrative expenses was due to an increase in employee-related expenses from *Rayaldee* and our international operating companies.

Research and development expenses. Research and development expenses for the three months ended March 31, 2023 and 2022 were $31.9 million and $12.3 million, respectively. Research and development expenses include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by the individual program for phase 3 clinical trials for drug approval and premarket approval for diagnostics tests, if any. Internal expenses include employee-related expenses such as salaries, benefits and equity-based compensation expenses. 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	Three months ended March 31,	
	2023	2022
External expenses:		
Manufacturing expense for biological products	$ 2,973	$ 1,250
Phase 3 studies	1,941	2,632
Post-marketing studies	129	17
Earlier-stage programs	18,150	2,601
Research and development employee-related expenses	7,808	5,173
Other internal research and development expenses	950	618
Third-party grants and funding from collaboration agreements	(73)	—
Total research and development expenses	$ 31,878	$ 12,291

The increase in research and development expenses for the three months ended March 31, 2023, was primarily due to a $12.5 million payment from us to Sanofi that accrued under the Sanofi In-License Agreement (each as defined in Note 14 to our condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q) and research expenses at ModeX, partially offset by lower expenses related to Somatrogon (hGH-CTP) due to the closure of the open-label extension studies in countries in which Somatrogon (hGH-CTP) received marketing authorization. Research and development expenses for the pharmaceutical segment for the three months ended March 31, 2023, and 2022 included equity-based compensation expenses of $835.9 thousand and $258.5 thousand, respectively.

Contingent consideration. Contingent consideration for the three months ended March 31, 2023, and 2022 was $0.1 million expense and $0.1 million reversal of expense, respectively. Contingent consideration for the three months ended March 31, 2023 and 2022 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 $16.4 million and $14.3 million, respectively, for the three months ended March 31, 2023 and 2022. 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.

Corporate

	For the three months ended March 31,			
(In thousands)	2023	2022	Change	% Change
Costs and expenses:				
Selling, general and administrative	$ 9,504	$ 10,969	(1,465)	(13)%
Research and development	38	(201)	239	119 %
Total costs and expenses	9,542	10,768	(1,226)	(11)%
Loss from operations	(9,542)	(10,768)	1,226	11 %

Operating loss for our unallocated corporate operations for the three months ended March 31, 2023, and 2022 was $9.5 million and $10.8 million, respectively, and principally reflects general and administrative expenses incurred in connection with our corporate operations. The decrease in operating loss for our unallocated corporate operations for the three months ended March 31, 2023, was due to a decrease in legal expenses partially offset by an increase in professional fees incurred.

Other

Interest income. Interest income for the three months ended March 31, 2023, and 2022 was $1.0 million and $0.0 million, respectively. The increase is driven by having higher average cash and investment balances as a result of the cash received related to the GeneDx Transaction, as well as increased interest rates between the two periods.

Interest expense. Interest expense for the three months ended March 31, 2023, and 2022 was $3.4 million and $2.7 million, respectively. Interest expense was principally related to interest incurred on the 2025 Notes, the 2023 Convertible Notes, and BioReference's outstanding debt under the Credit Agreement (each as defined in Note 7 to our condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q) with JPMorgan Chase Bank, N.A. ("CB").

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended March 31, 2023 and 2022, was $1.1 million and $0.1 million of expense, respectively. Derivative expense for the three months ended March 31, 2023 and 2022 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 March 31, 2023, and 2022 was $17.0 million of income and $(1.4) million of expense, respectively. Other income (expense), net for the three months ended March 31, 2023, included $8.3 million of income due to the increase in the fair value of our investment in GeneDx Holdings (as defined below). In addition, we recorded $8.5 million of income as a result of GeneDx Holdings achieving specific revenue targets for the fiscal year ending December 31, 2022. Other expense for the three months ended March 31, 2022, primarily consisted of foreign currency transaction gains recognized during the period.

Income tax benefit (provision). Our income tax benefit (provision) for the three months ended March 31, 2023 and 2022 was $(1.2) million and $21.3 million, respectively, and reflects quarterly results using our expected effective tax rate. For the three months ended March 31, 2023, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, the impact of the Merck Agreement and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have invested 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, 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 $37 thousand and $49 thousand for the three months ended March 31, 2023, and 2022, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2023, we had cash and cash equivalents of approximately $110.8 million. Cash used in operations of $22.6 million for the three months ended March 31, 2023 principally reflects milestone payments of $7.0 million and $2.5 million from Vifor and Nicoya, respectively, and general and administrative expenses related to our corporate operations and research and development activities. Cash provided by investing activities for the three months ended March 31, 2023 primarily reflects an investment of $5.0 million in GeneDx Holdings Class A common stock and capital expenditures of $3.0 million. Cash used in financing activities of $13.1 million primarily reflects net borrowings on our lines of credit and $3.0 million redemption of the 2033 Senior Notes. We have historically not generated sustained positive cash flow sufficient to offset our operating and other expenses, and our primary sources of cash have been from the public and private placement of equity, the issuance of the 2023 Convertible Notes, 2025 Notes and credit facilities available to us.

On March 8, 2023, ModeX, the Company (with respect to certain sections), and Merck entered into a License and Research Collaboration Agreement (the "Merck Agreement under") pursuant to which Merck obtained a license to certain patent rights and know-how in connection with the development of ModeX's preclinical nanoparticle vaccine candidate targeting the Epstein -Barr Virus. In consideration for the rights granted to Merck under the Merck Agreement, we received an initial one-time, non-refundable upfront payment of $50.0 million in April 2023. Certain of the rights subject to the license provided by us under the Merck Agreement were obtained by us from Sanofi pursuant to the Sanofi In-License Agreement stipulates, and because a portion of the upfront payment, milestones and royalties received by us under the Merck Agreement may be payable to Sanofi under the terms of the Sanofi In-License Agreement, we recorded $12.5 million in Accrued expenses in the accompanying Condensed Consolidated Balance Sheets.

On May 9, 2022, the Company entered into an Agreement and Plan of Merger (the "ModeX Merger Agreement"), pursuant to which we acquired ModeX. The Company paid the entirety of the $300.0 million purchase price in shares of Common Stock (the "Consideration Shares") to the former stockholders of ModeX. The Consideration Shares were valued at $219.4 million, based on the closing price per share of our Common Stock of $2.44 as reported by NASDAQ on the closing date, which reflected the deduction from the purchase price of the value of certain equity awards issued by the Company to ModeX employees in an aggregate amount equal to $12.4 million 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. The Company deposited 10% of the Consideration Shares in a twelve-month escrow for purposes of satisfying the potential indemnity obligations of the sellers under the ModeX Merger Agreement.

On April 29, 2022, the Company completed the disposition (the "GeneDx Transaction.") of its former subsidiary, GeneDx LLC (f/k/a GeneDx, Inc. "GeneDx"), to GeneDx Holdings Corp. (f/k/a "Sema Holdings Corp."), a Delaware corporation ("GeneDx Holdings"). 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 the Closing Shares (as defined in Note 1 to our condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q). 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 in cash or stock (at GeneDx Holdings' discretion) equal to a maximum of 30.9 million shares of GeneDx Holdings' Class A common stock if paid in stock (the "Milestone Consideration". 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 April 2022, Pfizer notified OPKO that NGENLA (Somatrogon), a once-weekly injection to treat pediatric growth hormone deficiency, has received pricing approval in Germany and Japan. NGENLA was granted marketing authorization by the Ministry of Health, Labour and Welfare in Japan and by the European Commission in January and February of 2022, respectively. With the achievement of these milestones, we received $85.0 million in milestone payments in 2022 under the Restated Pfizer Agreement.

In February 2019, we issued $200.0 million aggregate principal amount of the 2025 Notes in an underwritten public offering. The 2025 Notes bear interest at a rate of 4.50% per year, payable semiannually in arrears on February 15 and August 15 of each year. The 2025 Notes mature on February 15, 2025, unless earlier repurchased, redeemed or converted.

Holders may convert their 2025 Notes into shares of Common Stock at their option at any time prior to the close of business on the business day immediately preceding November 15, 2024, subject to the satisfaction of certain conditions. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our Common Stock, or a combination of cash and shares of our Common Stock, at our election.

The current conversion rate for the 2025 Notes is 236.7424 shares of Common Stock per $1,000 principal amount of 2025 Notes (equivalent to a conversion price of approximately $4.22 per share of Common Stock). The conversion rate for the 2025 Notes is subject to adjustment in certain events but will not be adjusted for any accrued and unpaid interest.

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 per share, at a conversion price of $5.00 per share of Common Stock. We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon upon no fewer than 30 days, and no more than 60 days, notice to the holders. The 2023 Convertible Notes contain customary events of default and representations and warranties of OPKO. On February 10, 2023, the Company amended the 2023 Convertible Notes to extend the maturity to January 31, 2025, and to reset the conversion price to the 10 day volume weighted average price immediately preceding the date of the amended note, plus a 25% conversion premium, or $1.66. In addition, under the terms of the 2023 Convertible Notes, interest will accrue from the most recent date to which interest has been paid or, if no interest has been paid, from the date of issuance, until the principal and accrued and unpaid interest, are paid in full. The remaining provisions of the 2023 Convertible Note were unchanged by such amendment.

As of March 31, 2023, the total commitments under our Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain were $53.5 million, of which $22.3 million was drawn as of March 31, 2023. At March 31, 2023, the weighted average interest rate on these lines of credit was approximately 5.4%. These lines of credit are short-term and are used primarily as a source of working capital. The highest aggregate principal balance at any time outstanding during the three months ended March 31, 2023 was $33.5 million. We intend to continue to draw under these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

The Credit Agreement provides for a $75.0 million secured revolving credit facility and includes a $20.0 million sub-facility for swingline loans and a $20.0 million sub-facility for the issuance of letters of credit. The Credit Agreement matures on August 30, 2024 and is guaranteed by all of BioReference's domestic subsidiaries, subject to certain exceptions. The Credit Agreement is also secured by substantially all assets of BioReference and its domestic subsidiaries, subject to certain exceptions, as well as a non-recourse pledge by us of our equity interest in BioReference. Availability under the Credit Agreement is based on a borrowing base composed of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein. As of March 31, 2023, $16.2 million remained available for borrowing under the Credit Agreement.

In connection with our agreements with Merck, Pfizer, Vifor, Nicoya and CAMP4, we are eligible to receive various milestone payments and royalty considerations. Under the terms of the Merck Agreement, we received an initial payment of $50.0 million and are also eligible to receive up to an additional $872.5 million upon the achievement of certain commercial and development milestones under several indications. We are also eligible to receive tiered royalty payments ranging from high single digits to low double digits upon achievement of certain sales targets of the Product (as defined in the Merck Agreement). Under the terms of the Restated Pfizer Agreement, we are eligible to receive up to an additional $275.0 million upon the achievement of certain regulatory milestones, including $85 million, which we received in 2022. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of Somatrogon (hGH-CTP) for adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of Somatrogon (hGH-CTP) for pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both Somatrogon (hGH-CTP) and Pfizer's Genotropin®. Under the terms of the Vifor Agreement, we are entitled to receive up to an additional $10 million in regulatory milestones and $207 million in milestone payments tied to the launch, pricing and sales of Rayaldee, including a $7.0 million regulatory milestone payment we recorded in the first quarter of 2023 triggered by the German price approval for Rayaldee and $3.0 million regulatory milestone payment we recognized in 2022 following the first sale of Rayaldee in Europe. In addition, we are eligible to receive tiered, double-digit royalty payments. Under the terms of the Nicoya Agreement, we received an initial upfront payment of $5 million and are eligible to receive an aggregate of $5 million tied to the first anniversary of the effective date of the Nicoya Agreement, of which we have received $2.5 million. Furthermore, we received the additional $2.5 million upon Nicoya's submission of the investigational new drug application to the Center for Drug Evaluation of China in March 2023. We are also eligible to receive up to an additional aggregate amount of $115 million upon the achievement of certain development, regulatory and sales-based milestones by Nicoya for the Nicoya Product in the Nicoya Territory. We are also eligible to receive tiered, double digit royalty payments at rates in the low double digits on net product sales within the Nicoya Territory and in the Nicoya Field. Under the terms of the CAMP4 Agreement, we received an initial upfront payment of $1.5 million and we are eligible to receive up to $3.5 million in development milestone payments for Dravet syndrome products and $4.0 million for non-Dravet syndrome products, as well as sales milestones of up to $90 million for Dravet syndrome products and up to $90 million for non-Dravet syndrome products.

In connection with our acquisitions of CURNA, OPKO Diagnostics and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events, including up to an additional $19.1 million in shares of our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones; and up to an additional $125.0 million in either shares of our Common Stock or cash, at our option subject to the achievement of certain milestones, to the former shareholders of OPKO Renal. As a result of our execution of the CAMP4 Agreement, we will have to pay a percentage of any payments received under the CAMP4 Agreement to the former CURNA stockholders.

We believe that the cash and cash equivalents on hand at March 31, 2023 and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements, and the timing of those requirements, will depend on a number of factors, including the evolving impact of the COVID-19 pandemic on our business, the approval and success of our products in development, particularly our long acting Somatrogon (hGH-CTP) for which we have received approval in Europe, Japan, Australia and Canada, submitted for approval in the U.S. and received a Complete Response Letter in January 2022, the approval and success of Somatrogon (hGH-CTP) outside the United States, including in Europe, Japan, Australia and Canada, the commercial success of *Rayaldee*, BioReference's financial performance, possible acquisitions and dispositions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, our success in developing markets for our product candidates and results of government investigations, payor claims, and legal proceedings that may arise, including, without limitation class action and derivative litigation to which we are subject, and our ability to obtain insurance coverage for such claims. We have historically not generated sustained positive cash flow and if we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions or reduce our marketing or sales efforts or cease operations.

Additionally, the rapid development and fluidity of the COVID-19 pandemic and new variants of the virus makes it very difficult to predict its ultimate impact on our business, results of operations and liquidity. The pandemic presents a significant uncertainty that could materially and adversely affect our results of operations, financial condition and cash flows. For example, testing needs for COVID-19 decreased significantly as a result of declining infection rates and the normalization of living with COVID-19 following the increase in accessibility to COVID-19 vaccines and antiviral treatments, which negatively impacted our COVID-19-related diagnostics testing services provided by BioReference and our results of operations, which had been positively affected by COVID-19 during 2020 and 2021. The combination of potential disruptions to our business resulting from COVID-19 together with and volatile credit and capital markets could adversely impact our future liquidity, which could have an adverse effect on our business and results of operations. We will continue to monitor and assess the impact COVID-19 and new variants of the virus may have on our business and financial results.

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 obligations in connection with clinical trials, which span over two years, and that depend on patient enrollment. The total amount of expenditures is dependent on the actual number of patients enrolled and as such, the contracts do not specify the maximum amount we may owe.
- Product license agreements effective during the lesser of 15 years or patent expiration whereby payments and amounts are determined by applying a royalty rate on uncapped future sales.
- Contingent consideration that includes payments upon achievement of certain milestones including meeting development milestones such as the completion of successful clinical trials, NDA approvals by the FDA and revenue milestones upon the achievement of certain revenue targets all of which are anticipated to be paid within the next seven years and are payable in either shares of our Common Stock or cash, at our option, and that may aggregate up to $141.8 million.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

There were no material changes to our critical accounting policies and estimates described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 that have had a material impact on our Condensed Consolidated Financial Statements and related notes.

RECENT ACCOUNTING PRONOUNCEMENTS

Recently adopted accounting pronouncements.

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)." ASU 2020-06 simplifies the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. The ASU is effective for public entities for fiscal years beginning after December 15, 2021, with early adoption permitted. As required, we adopted ASU 2020-06 on January 1, 2022 and used the modified retrospective approach for all convertible debt instruments at the beginning of the period of adoptions. Results for reporting periods beginning January 1, 2022 are presented under ASU 2020-06, while prior period amounts were not adjusted and continue to be reported in accordance historic accounting guidance.

Under the modified approach, entities will apply the guidance to all financial instruments that are outstanding as of the beginning of the year of adoption with the cumulative effect recognized as an adjustment to the opening balance of retained earnings. ASU 2020-06 eliminates the cash conversion and beneficial conversion feature models in ASC 470-20 that require an issuer of certain convertible debt and preferred stock to separately account for embedded conversion features as a component of equity. The adoption of ASU 2020-06 at January 1, 2022 resulted in an increase of the Convertible notes of $25.6 million, a reduction of the Accumulated deficit of $17.5 million and a reduction of Additional paid-in capital of $39.1 million.

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 exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. Both the exposed transactions and the hedging contracts are translated and fair valued, respectively, at current spot rates, with gains and losses included in earnings.

Our derivative activities, which consist of foreign exchange forward contracts, are initiated to economically hedge forecasted cash flows that are exposed to foreign currency risk. The foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity dates. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the Condensed Consolidated Statements of Operations and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. If the counterparties to the exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. Our foreign exchange forward contracts primarily hedge exchange rates on the Chilean Peso to the U.S. dollar. If Chilean Pesos were to strengthen or weaken in relation to the U.S. dollar, our loss or gain on hedged foreign currency cash-flows would be offset by the derivative contracts, with a net effect of zero.

Approximately 18.5% of revenue for the three months ended March 31, 2023, and approximately 10.9% of revenue for the three months ended March 31, 2022, were denominated in currencies other than the U.S. Dollar (USD). Our financial statements are reported in USD and, accordingly, fluctuations in exchange rates will affect the translation of revenues and expenses denominated in foreign currencies into USD for purposes of reporting the consolidated financial results. In the first quarter of 2023 and during the year ended December 31, 2022, the most significant currency exchange rate exposures were the Euro and Chilean Peso. Gross accumulated currency translation adjustments recorded as a separate component of shareholders' equity were $34.2 million and $39.9 million at March 31, 2023 and December 2022, respectively. For information on such open foreign exchange forward contracts for the three months ended March 31, 2023 and 2022 see "Management's Discussion and Analysis—Results of Operations— Foreign Currency Exchange Rates."

We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or "other than trading" instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price, or equity price risk.

Interest Rate Risk – Our exposure to interest rate risk relates to our cash and investments and to our borrowings. We generally maintain an investment portfolio of money market funds and marketable securities. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment.

At March 31, 2023, we had cash and cash equivalents of $110.8 million. The weighted average interest rate related to our cash and cash equivalents for the three months ended March 31, 2023 was less than 1%. As of March 31, 2023, the principal outstanding balances under BioReference's Credit Agreement with CB and our Chilean and Spanish lines of credit was $22.3 million in the aggregate at a weighted average interest rate of approximately 5.4%.

Our $55.0 million aggregate principal amount of our 2023 Convertible Notes has a fixed interest rate of 5%, and our $200.0 million aggregate principal amount of the 2025 Notes has a fixed interest rate of 4.50%, and therefore are not subject to fluctuations in market interest rates.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we may invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and money market funds that invest in such debt instruments, and, by policy, restrict our exposure to any single corporate issuer by imposing

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.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, management concluded that our disclosure controls and procedures were effective as of March 31, 2023.

Changes to the Company's Internal Control Over Financial Reporting

There have been no changes to the Company's internal control over financial reporting that occurred during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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 State of Texas ("TX OAG") informed BioReference that it believes that, from 2005 to February 2023, BioReference may have violated the Texas Medicaid Fraud Prevention Act with respect to claims it presented to Texas Medicaid for reimbursement. BioReference has not determined whether there is any merit to the TX OAG claims nor can it determine the extent of any potential liability. While management cannot predict the outcome of this matters at this time, the ultimate outcome could be material to our business, financial condition, results of operations, and cash flows.

See Note 12 to the interim unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for information regarding the status of legal proceedings involving the Company, which information is incorporated by reference herein.

Item 1A. Risk Factors

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 2022.

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*+	License and Research Collaboration Agreement by and between ModeX Therapeutics, Inc., OPKO Health, Inc. (with respect to certain sections), and Merck Sharp & Dohme LLC dated March 7, 2023.
Exhibit 10.2	Form of Amended 5% Convertible Promissory Note dated February 10, 2023, filed as Exhibit 10.22 with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2023, and incorporated herein by reference.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended March 31, 2023.
Exhibit 31.2	Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended March 31, 2023.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended March 31, 2023.
Exhibit 32.2	Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended March 31, 2023.
Exhibit 101.INS	Inline XBRL Instance Document
Exhibit 101.SCH	Inline XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	inline XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Pursuant to Item 601(b)(10)(iv) of Regulation S-K, portions of this exhibit have been omitted because the Company customarily and actually treats the omitted portions as private or confidential, and such portions are not material and is the type that the Company treats as private and confidential. The Company will supplementally provide a copy of an unredacted copy of this exhibit to the U.S. Securities and Exchange Commission or its staff upon request.

\+ Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 3, 2023

OPKO Health, Inc.

/s/ Adam Logal

Adam Logal

Senior Vice President and Chief Financial Officer

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 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/ Phillip Frost, M.D.

Phillip Frost, M.D.
Chief Executive Officer

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.

Date: May 3, 2023

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.

Chief Executive Officer

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 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.

Date: May 3, 2023

/s/ Adam Logal

Adam Logal

Senior Vice President and Chief Financial Officer

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

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 [***]

LICENSE AND RESEARCH COLLABORATION AGREEMENT

This License and Research Collaboration Agreement (this "**Agreement**") is effective as of March 7, 2023 (the "**Effective Date**") and is entered into by and among MODEX THERAPEUTICS, INC., a corporation organized and existing under the laws of Delaware ("**ModeX**"), solely for purposes of Sections 6.1 and 9.3, OPKO HEALTH, INC., a corporation organized and existing under the laws of Delaware ("**OPKO**"), and MERCK SHARP & DOHME LLC, a limited liability company organized and existing under the laws of New Jersey ("**Merck**").

RECITALS:

WHEREAS, ModeX has developed ModeX Know-How and has rights to ModeX Patent Rights;

WHEREAS, Merck and ModeX desire to enter into a research collaboration to Develop Vaccines and Products, upon the terms and conditions set forth herein;

WHEREAS, Merck intends to pursue such Development in the EBV Field, which may include infectious mononucleosis, multiple sclerosis, and oncology indications, where appropriate, as contemplated by the Merck Development Plan; and

WHEREAS, Merck desires to obtain a license under the ModeX Patent Rights and ModeX Know-How upon the terms and conditions set forth herein, and ModeX desires to grant such a license;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, ModeX and Merck hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless specifically set forth to the contrary herein, the following terms, whether used in the singular or plural, shall have the respective meanings set forth below.

1.1 "**AAALAC**" shall mean the Association for Assessment and Accreditation of Laboratory Animal Care International.

1.2 "**Accounting Standards**" means the then-current financial reporting standards followed by a Party or its Affiliates, sublicensees, or subcontractors, examples of which are IFRS (International Financial Reporting Standards) and GAAP (United States generally accepted accounting principles), in each case consistently applied.

1.3 "**Acquired Party**" shall have the meaning set forth in Section 1.16.

1.4 "**Acquiring Entity**" shall mean, collectively, (a) the Third Party referenced in the definition of Change of Control, and (b) such Third Party's Affiliates, other than the Acquired Party in the definition of Change of Control and such Acquired Party's Affiliates, determined immediately prior to the closing of such Change of Control.

1.5 "**Act**" shall mean, as applicable, the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., or the Public Health Service Act, 42 U.S.C. §§ 262 et seq., each as amended from time to time.

1.6 "**Affiliate**" shall mean, with respect to a Person: (a) any corporation or business entity of which, now or hereafter, more than fifty percent (50%) of the securities or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by such Person; or (b) any corporation or other business entity which, now or hereafter, directly or indirectly, owns, controls or holds more than fifty percent (50%) (or the maximum ownership interest permitted by Applicable Law) of the securities or other ownership interests representing the equity, the voting stock or, if applicable, the general partnership interest, of such Person; or (c) any corporation or business entity of which, now or hereafter, more than fifty percent (50%) of the securities

or other ownership interests representing the equity, the voting stock or general partnership interest are owned, controlled or held, directly or indirectly, by a corporation or business entity described in (a) or (b).

1.7 "**Agreement**" shall have the meaning given such term in the preamble to this document.

1.8 "**Agreement Payments**" shall have the meaning set forth in Section 5.7.

1.9 "**Alliance Manager**" shall have the meaning set forth in Section 2.4.1.

1.10 "**Applicable Law**" shall mean any and all laws of any jurisdiction that are applicable to either of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates carrying out the activities hereunder is subject, and will include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, arbitral body, board, or court or any central, state, or provincial government or local authority or other governmental authority in such jurisdictions, including Good Laboratory Practices, Good Clinical Practices and Good Manufacturing Practices.

1.11 "**Biosimilar Application**" shall have the meaning set forth in Section 7.3.8.

1.12 "**Business Day**" shall mean any day other than a Saturday, Sunday, or a day on which commercial banks located in the jurisdiction where the applicable obligations are to be performed are authorized or required by law to be closed.

1.13 "**Calendar Quarter**" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31, except that the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the then-current Calendar Quarter, and the last Calendar Quarter of the Term shall end on the last day of the Term.

1.14 "**Calendar Year**" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall end on the last day of the Term.

1.15 "**CDMO**" shall have the meaning set forth in Section 2.12.

1.16 "**Change of Control**" shall mean, with respect to a Party (the "**Acquired Party**"), (a) the sale to a Third Party of all or substantially all of such Acquired Party's assets or business relating to ***; (b) a merger, reorganization or consolidation involving such Acquired Party, as the case may be, in which the voting securities of such Acquired Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a Third Party, or group of such Persons acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Acquired Party. Notwithstanding the foregoing, the following shall not constitute a Change of Control: (i) ***; (ii) ***; or (iii) ***.

1.17 "**Clinical Trial**" shall mean a Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, or post-approval study.

1.18 "**CMC Development**" means the chemistry, manufacturing, and controls (CMC)-related Development activities related to the composition, manufacture, and specification of a Vaccine or Product intended to assure the proper identification, quality, purity, and strength thereof. CMC Development includes test method development and stability testing, process development, process improvements (improving product robustness or manufacturing efficiencies), drug substance development, process qualification, process and method validation, process scale-up, formulation development, delivery system development, QA and QC development.

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 fully described in Section 2.3.

1.26 "**Competing Pharma**" shall mean a company or group of companies acting in concert (a) that is *** that preceded the date of determination, or (b) which has ***.

1.27 "**Competing Product**" shall mean:

(a) during the period commencing on *** thereafter, ***; and

(b) following the period described in (a) ***.

1.28 "**Competitive Infringement**" shall have the meaning set forth in Section 7.3.1.

1.29 "**Control**", "**Controls**" or "**Controlled by**" shall mean, with respect to any item of or right under any Know-How, Patent Rights, or other intellectual property assets or rights, as applicable, the possession of (whether by ownership or license, other than pursuant to this Agreement) or the ability of a Party to transfer or grant access to, or a license or sublicense of, such items or right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing at the time such Party would be required hereunder to transfer or grant the other Party such access or license or sublicense. However, a Party (or an Affiliate of a Party, as applicable) shall be deemed not to Control any Patent Rights or Know-How or other rights ***.

1.30 "**Develop**", or "**Developing**" or "**Development**" shall mean (a) to research, develop, analyze, test and conduct preclinical, clinical and all other regulatory trials for a compound, vaccine, or product (including a Vaccine or a Product), including new Indications, (b) all activities pertaining to CMC Development and formulation development, including new formulations, and (c) all other activities related to securing and maintaining Marketing Authorization for a compound, vaccine, or product, and regulatory activities in connection therewith.

1.31 "**Development Milestone Event**" shall have the meaning set forth in Section 5.2.1.

1.32 "**Development Milestone Payments**" shall have the meaning set forth in Section 5.2.1.

1.33 "**Dispute**" shall have the meaning set forth in Section 9.8.1.

1.34 "**EBV**" shall mean Epstein-Barr Virus.

1.35 "**EBV Field**" shall mean the treatment, prophylaxis or diagnosis of disease associated with EBV, which may include infectious mononucleosis, Hodgkin's lymphoma, Burkitt lymphoma, post-transplant lymphoma, gastric cancer, nasopharyngeal carcinoma, and multiple sclerosis.

1.36 "**Effective Date**" shall have the meaning given such term in the preamble to this document.

1.37 "**European Major Market**" shall mean any one of the following countries: the ***.

1.38 "**Excluded Claim**" shall have the meaning set forth in Section 9.8.3.

1.39 "**Exclusions Lists**" shall have the meaning set forth in Section 1.122.

1.40 "**Field**" shall mean (a) with respect to any sublicense granted by ModeX to Merck of ***; and (b) in all other cases, ***.

1.41 "**First Commercial Sale**" shall mean, with respect to any Product, the first sale for end use or consumption of such Product in a country, excluding, however, ***.

1.42 "**GCP**" or "**Good Clinical Practices**" shall mean the applicable then-current Good Clinical Practices as such term or its equivalent is defined from time to time by the United States Food and Drug Administration or other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in the Territory pursuant to its regulations, guidelines or otherwise, as applicable.

1.43 "**GLP**" or "**Good Laboratory Practice**" shall mean the applicable then-current standards for laboratory activities for pharmaceuticals or biologicals, as set forth in the Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with any similar standards of good laboratory practice as are required by any Regulatory Authority in the Territory.

1.44 "**GMP**" or "**Good Manufacturing Practices**" shall mean the applicable then-current Good Manufacturing Practices as such term or its equivalent is defined from time to time by the United States Food and Drug Administration or other relevant Regulatory Authority having jurisdiction over the Development, Manufacture or Commercialization of Product in the Territory pursuant to its regulations, guidelines or otherwise, as applicable.

1.45 "**Guaranteed Obligations**" shall have the meaning set forth in Section 9.3.

1.46 "**Improvement**" shall mean, with respect to ModeX Know-How described in subpart (a) of the "ModeX Know-How" definition and licensed hereunder, any improvement, modification, refinement, or correction of such ModeX Know-How which is any of the following: (a) a *** that (i) is *** and (ii) results in a *** that is ***; or (b) a ***.

1.47 "**IND**" shall mean an Investigational New Drug Application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct Clinical Trials filed with or submitted to a Regulatory Authority in conformance with the requirements of such Regulatory Authority.

1.48 "**Indemnified Party**" shall have the meaning set forth in Section 6.5.3.

1.49 "**Indemnifying Party**" shall have the meaning set forth in Section 6.5.3.

1.50 "**Indication**" shall mean a separate and distinct disease or medical condition in humans which a Product that is in Clinical Trials is intended to treat, prevent, or diagnose or for which a Product has received Marketing Authorization. For clarity, with respect to a particular tumor type (such as lung or head and neck, for example), all subtypes of such tumor type, all treatments of such tumor type (including

all lines of treatment), and different patient populations within such tumor type, constitute the same Indication. For further clarification and as an example, Burkett's lymphoma, Hodgkin's lymphoma, gastric carcinoma, nasopharyngeal carcinoma, and post-transplant lymphomas would each constitute separate Indications.

1.51 "**Information**" shall mean any and all information and data, including trade secrets, all Merck Know-How, all ModeX Know-How, and all other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, which is provided by one Party to the other Party in connection with this Agreement.

1.52 "**Initiates**", or "**Initiated**" or "**Initiation**" shall mean, with respect to a Clinical Trial, the administration of the first dose to a patient or subject in such Clinical Trial.

1.53 "**Invention**" shall mean any process, method, composition of matter, article of manufacture, discovery or finding that is conceived or reduced to practice as a result of the Research Program.

1.54 "**Joint Information and Inventions**" shall mean all Know-How resulting from the Research Program developed or invented jointly by (a) employee(s) of Merck or its Affiliates, or a Third Party acting on behalf of Merck or its Affiliates, on the one hand, and (b) employee(s) of ModeX or its Affiliates, or a Third Party acting on behalf of ModeX or its Affiliates, on the other hand, but ***.

1.55 "**Joint Patent Rights**" shall mean all Patent Rights that claim or cover Joint Information and Inventions.

1.56 "**Know-How**" shall mean all information and materials, including all discoveries, improvements, processes, methods, protocols, formulas, data, inventions (including Inventions), know-how and trade secrets, patentable or otherwise.

1.57 "**Licensed Intellectual Property**" shall mean all ModeX Patent Rights, ModeX Know-How, and ModeX's interest in all Joint Patent Rights.

1.58 "**Manufacture**" shall mean, with respect to a compound, vaccine, or product (including a Vaccine and Product), including other active pharmaceutical ingredients in a product, the receipt, handling and storage of active pharmaceutical ingredients and other materials, the manufacturing, processing, packaging and labeling (excluding the development of packaging and labeling components for Marketing Authorization), holding (including storage), quality assurance and quality control testing (including release) of such compound, vaccine, or product (other than quality assurance and quality control related to development of the manufacturing process, which activities shall be considered Development activities) and shipping of such compound, vaccine, or product.

1.59 "**Manufacturing Party**" shall have the meaning set forth in Section 2.12.

1.60 "**Marketing Authorization**" shall mean *** approvals from the relevant Regulatory Authority necessary to market and sell a Product in any country (***).

1.61 "**Material Safety Issue**" means *** good-faith determination that there is an unacceptable risk for harm in humans based upon the ***.

1.62 "**Merck**" shall have the meaning given such term in the preamble to this Agreement.

1.63 "**Merck Development Plan**" shall mean the development plan attached hereto as Schedule 1.63.

1.64 "**Merck Indemnified Parties**" shall have the meaning set forth in Section 6.5.1.

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 [***]

1.65 "**Merck Information and Inventions**" shall mean all (a) Know-How resulting from the Research Program developed or invented solely by employee(s) of Merck or its Affiliates, or a Third Party acting on behalf of Merck or its Affiliates, and not employed by ModeX or its Affiliates and (b) all Merck Proprietary Adjuvant IP.

1.66 "**Merck Know-How**" shall mean ***.

1.67 "**Merck Patent Rights**" shall mean ***.

1.68 "**Merck Proprietary Adjuvant**" shall mean ***.

1.69 "**Merck Proprietary Adjuvant IP**" shall mean ***.

1.70 "**Merck Proprietary Formulation**" shall mean ***.

1.71 "**Merck Proprietary Formulation IP**" shall mean ***.

1.72 "***" shall have the meaning set forth in Section 2.3.2.

1.73 "**ModeX**" shall have the meaning given such term in the preamble to this Agreement.

1.74 "**ModeX Indemnified Parties**" shall have the meaning set forth in Section 6.5.2.

1.75 "**ModeX Information and Inventions**" shall mean all Know-How resulting from the Research Program developed or invented solely by employee(s) of ModeX or its Affiliates, or a Third Party acting on behalf of ModeX or its Affiliates, and not employed by Merck or its Affiliates, excluding, ***.

1.76 "**ModeX Know-How**" shall mean all Know-How (including ModeX Information and Inventions and ModeX's rights in Joint Information and Inventions) that: (a) (i) is or was Controlled by ModeX as of the Effective Date or is Controlled by ModeX during the Term, (ii) is not generally known, and (iii) is necessary or useful for the performance of Merck's obligations under the Research Plan or for the Development, Manufacture, or Commercialization of Vaccines or Products in the Field in the Territory; or (b) (i) is Controlled by an Affiliate of ModeX after the Effective Date but during the Term; (ii) is not generally known; (iii) constitute Improvements to the Know-How described in clause (a) of this definition, and (iv) is necessary or useful for the performance of Merck's obligations under the Research Plan or for the Development, Manufacture, or Commercialization of Vaccines or Products in the Field in the Territory, excluding, however, ***.

1.77 "**ModeX Patent Rights**" shall mean Patent Rights which: (a) are Controlled by ModeX as of the Effective Date or during the Term and satisfy any of the following: (i) claim or cover any Vaccine or Product, or a method of use or process of Manufacture thereof, including any improvements; (ii) claim or cover ModeX Know-How; or (iii) are necessary or useful for the Development, Manufacture, or Commercialization of Vaccines or Products in the Field in the Territory; or (b) are Controlled by an Affiliate of ModeX after the Effective Date but during the Term and (i) claim or cover any Vaccine or Product (but solely to the extent such Patent Rights claim or cover any Vaccine or Product), or a method of use or process of manufacture thereof, or (ii) claim or cover any ModeX Know-How described in clause (b) of the definition thereof. The ModeX Patent Rights include the Patent Rights listed on Schedule 1.77.

1.78 "**ModeX Platform**" shall mean the proprietary ferritin nanoparticle technology-based platform Controlled by ModeX.

1.79 "**ModeX Product Patent Rights**" shall have the meaning set forth in Section 7.1.1(b).

1.80 "***" shall have the meaning set forth in Section 2.3.2.

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 of a Product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.83 "**Net Sales**" shall mean the gross invoice price (***) of Product sold by Merck or its Related Parties to the first Third Party after deducting, if not previously deducted, from the amount invoiced or received the following deductions determined in accordance with Accounting Standards as consistently applied from such gross amounts which are actually incurred, allowed, accrued or specifically allocated to the Product:

(a) normal and customary trade and quantity discounts ***;

(b) returns, rebates, chargebacks, and other allowances;

(c) retroactive *** ;

(d) *** or other governmental authorities;

(e) a *** of the amount ***; and

(f) the standard *** administering Product.

With respect to sales of Combination Products, ***. The *** set forth *** will be applied in calculating Net Sales for a Combination Product. In the event that Product *** other means of calculating Net Sales with respect to Combination Products.

1.84 "**Net Sales Report**" shall have the meaning set forth in Section 5.4.

1.85 "**NIH**" shall mean, collectively, the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration, which are agencies within the Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Disease and/or the National Institutes of Health, or any successor in interest thereto.

1.86 "**NIH Agreement**" shall mean the nonexclusive patent license agreement, dated on or about the date hereof, by and between NIH and Merck (or its Affiliate), with respect to the following ***, a copy of which has been provided to ModeX as of the date hereof.

1.87 "**Officials**" shall have the meaning set forth in Section 2.10.3.

1.88 "**Party**" shall mean Merck or ModeX, individually, and "**Parties**" shall mean Merck and ModeX, collectively.

1.89 "**Patent Rights**" shall mean any and all patents and patent applications in the Territory (which, for the purpose of this Agreement, shall be deemed to include certificates of invention and applications for certificates of invention), including divisionals, continuations, continuations-in-part, reissues, renewals, substitutions, registrations, re-examinations, revalidations, extensions, supplementary protection certificates, pediatric exclusivity periods and the like of any such patents and patent applications, and foreign equivalents of the foregoing.

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 [***]

1.90 "**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 applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement or pricing of a Product in the Territory, including, in the United States, the United States Food and Drug Administration and any successor governmental authority having substantially the same function.

1.98 "***" means, with respect *** the period of time during which ***.

1.99 "***" shall mean *** for the Product in the Field in the Territory.

1.100 "**Related Party**" shall mean, with respect to a Party, each of such Party, its Affiliates, and their respective sublicensees (which term does not include distributors), as applicable.

1.101 "**Research Executives**" shall have the meaning set forth in Section 2.3.2.

1.102 "**Research Plan**" shall mean, with respect to the Research Program, the written plan setting forth the research and other Development activities to be undertaken by the Parties in accordance with this Agreement, as set forth in Exhibit A.

1.103 "**Research Program**" shall mean the program of research and other Development activities related to the Development of a Vaccine or Product undertaken by the Parties as set forth in Article 2 and the applicable Research Plan.

1.104 "**Research Term**" shall have the meaning set forth in Section 2.8.1.

1.105 "**Reversion License**" shall have the meaning set forth in Section 8.4.2.

1.106 "**Reverted Products**" shall have the meaning set forth in Section 8.4.2.

1.107 "***" means any ***.

1.108 "**Royalty Period**" shall have the meaning set forth in Section 5.3.1(d).

1.109 "***" means ***.

1.110 "**Sanofi In-License Agreement**" shall mean that certain License Agreement entered into as of July 1, 2021 between ModeX and Sanofi, a French corporation ("**Sanofi**").

1.111 "**Sanofi Letter Agreement**" shall mean that certain letter agreement among Sanofi, Merck, and ModeX, dated as of the date hereof.

1.112 "**Sanofi Patents**" shall mean any ModeX Patent Rights which are Controlled by ModeX pursuant to licenses granted under the Sanofi In-License Agreement.

1.113 "**Supporting Documents**" shall have the meaning set forth in Section 8.4.2(f).

1.114 "**Taxes**" shall have the meaning set forth in Section 5.7.

1.115 "**Term**" shall have the meaning set forth in Section 8.1.

1.116 "**Territory**" shall mean all of the countries in the world, and their territories and possessions.

1.117 "**Third Party**" or "**Third-Party**" shall mean an entity other than Merck, ModeX, or their Affiliates.

1.118 "**Third-Party Licenses**" shall have the meaning set forth in Section 5.3.4.

1.119 "***" shall have the meaning set forth in Section 8.4.1.

1.120 "**Vaccine**" shall mean any multivalent or monovalent vaccine assembled using the ModeX Platform and displaying *** following:

(a) a ***;

(b) a ***; or

(c) a ***

which in any case *** may include one or more ***, but in *** must *** responses to EBV.

1.121 "**Valid Patent Claim**" shall mean, with respect to a particular country, (a) *** and that (i) has ***, and (ii) has *** or (b) any ***, it will *** for purposes of this Agreement ***.

1.122 "**Violation**" shall mean that either a Party, or any of its officers or directors has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (**https://oig.hhs.gov/exclusions/index.asp**); and/or (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (**https://oig.hhs.gov/exclusions/exclusions_list.asp**) or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (**https://sam.gov/content/exclusions**) (each of (a) and (b), singly and collectively, the "**Exclusions Lists**").

ARTICLE 2
RESEARCH PROGRAM

2.1 **General**. ModeX and Merck shall engage in the Research Program upon the terms and conditions set forth in this Agreement. The activities to be undertaken in the course of the Research Program are set forth the Research Plan, which may be amended from time to time in accordance with this Agreement.

2.2 **Conduct of Research**. ModeX and Merck each shall proceed diligently with the work set out in the Research Program by using their respective reasonable efforts to allocate sufficient time, effort, equipment and facilities to the Research Program and to use personnel with sufficient skills and

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**. The Research Program shall be conducted under the direction of a joint steering committee (the "**Committee**") comprised of *** of Merck (who shall be employees of Merck or its Affiliate, as applicable) and *** of ModeX (who shall be employees of ModeX or its Affiliate, as applicable), until such time that the Committee is transitioned to an advisory committee in accordance with Section 2.3.6, following which the Committee will be comprised of *** of each Party (who *** with appropriate technical credentials, experience, and knowledge, and ongoing familiarity with the Research Program). Subject to the preceding sentence, each Party may change its representatives to the Committee from time to time in its sole discretion, effective upon notice to the other Party of such change. These representatives shall have appropriate technical credentials, experience and knowledge, and ongoing familiarity with the Research Program. Additional representative(s) or consultant(s) may from time to time, by mutual consent of the Parties, be invited to attend Committee meetings, subject to such representative's or consultant's written agreement to comply with the requirements of Section 4.1. The Committee shall be ***.

2.3.2 **Decision-Making Authority**. Until the Committee is transitioned to an advisory committee in accordance with Section 2.3.6, decisions of the Committee shall be made *** by the representatives. In the event that the Committee cannot or does not, after reasonable efforts, reach agreement on an issue (including with respect to any matter set forth in Section 2.3.3) within *** after such matter has been referred to the Committee, then the matter shall be escalated to the *** (or his or her designee) (the "***") and the *** (the "***" and together with the ***, collectively, the "**Research Executives**") who shall endeavor to facilitate a resolution of such matter, but if such matter is still not resolved within *** then the resolution or course of conduct shall be determined by *** after giving due consideration to *** (and, for clarity, such matter shall not be subject to the dispute resolution mechanisms set forth in Section 9.8).

2.3.3 **Scope of Committee Oversight**. Until the Committee is transitioned to an advisory committee in accordance with Section 2.3.6, the Committee shall be responsible for overseeing the Research Program, including to (a) review, amend and approve the Research Plan from time to time; (b) review and coordinate the Parties' activities under the Research Plan, including, for example, ModeX's use of subcontractors to perform Research Program activities; (c) confer regarding the status of the Research Program, confer regarding the progress under the Research Plan, and make determinations and decisions in connection with activities thereunder (including issues of priority); (d) review relevant data under the Research Program; (e) consider and advise on any technical issues that arise under the Research Program; (f) oversee the CMC Development and Manufacturing activities of the CDMO engaged by the Manufacturing Party under Section 2.12; (g) oversee the initial manufacturing technology transfer contemplated under Section 2.5; (h) conduct and oversee developability and preclinical immunogenicity studies, ensure technology transfer, and provide strategic oversight; (i) review written progress reports to be provided by each Party in advance of each meeting describing the work performed by or on behalf of such Party (or its sublicensees) to date on the Research Program and such other information as may be required by the Research Plan; and (j) determine such other matters as allocated to the Committee hereunder. Within *** after each meeting of the Committee, *** shall provide to *** a written summary of the Parties' progress under the Research Program since the previous Committee meeting, which report may be *** to the extent required by ***, it being understood that any such reports from *** shall be the confidential Information of *** (with respect to *** Information) and *** (with respect to *** Information, even though such report is prepared by ***), and shall be *** subject to obligations of confidentiality substantially similar to those contained herein.

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 a manner that would conflict with the express terms and conditions of this Agreement; or (d) amend the Research Plan in a manner that would (i) *** to practice any ***; or (ii) ***; provided that, for the avoidance of doubt, ***.

2.3.5 **Meetings**. The Committee shall meet in accordance with a schedule established by mutual written agreement of the Parties, but no *** during the Research Term and no *** thereafter until disbandment, with the location for such meetings alternating between ModeX and Merck facilities (or such other location may be determined by the Committee). Alternatively, the Committee may meet by means of teleconference, videoconference, or other similar communications equipment. Each Party shall ***. Upon the later of (a) completion of the Research Plan or (b) completion of the initial manufacturing technology transfer contemplated under Section 2.5, the Committee shall have a final meeting in its decision-making capacity to review the results of the Research Program and then shall be transitioned to an advisory committee in accordance with Section 2.3.6.

2.3.6 **Transition to Advisory Committee; Disbandment of Committee**. Upon the later of (a) completion of the Research Plan or (b) completion of the initial manufacturing technology transfer contemplated under Section 2.5, the Committee shall cease to have any decision-making authority under this Agreement, and shall serve solely in an advisory capacity, and its purview shall be limited to (i) the sharing of information and facilitation of discussion about the status of the Vaccines and Products and (ii) reviewing results and providing input regarding Development efforts in connection with the Vaccine and Products, including for example ***. Upon ***, or such earlier date as the Parties may mutually agree in writing, the Committee shall be disbanded. For clarity, once the Committee has transitioned to an advisory capacity but prior to ***, or such earlier date as the Parties may mutually agree in writing, the Committee shall meet in person or by alternative means as described in Section 2.3.5 no ***. Within *** after each meeting of the advisory Committee as contemplated by this Section 2.3.6, *** shall provide to *** a written summary of *** which report may be provided ***, it being understood that any such *** shall be the confidential Information of ***, and shall be *** subject to obligations of confidentiality substantially similar to those contained herein.

2.4 **Alliance Managers**.

2.4.1 **Appointment**. Each Party shall have the right to appoint an employee who shall oversee interactions between the Parties for all matters related to this Agreement (each an "**Alliance Manager**"). Such persons shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information and may serve as a single point of contact for any matters arising under this Agreement. The Alliance Managers shall have the right to attend all Committee meetings as non-voting participants and may bring to the attention of the Committee any matters or issues either of them reasonably believes should be discussed, and shall have such other responsibilities as the Parties may mutually agree in writing. Each Party may designate different Alliance Managers by notice in writing to the other Party.

2.4.2 **Responsibilities of the Alliance Managers**. The Alliance Managers, if appointed, shall have the responsibility of creating and maintaining a constructive work environment between the Parties. Without limiting the generality of the foregoing, each Alliance Manager shall:

(a) identify and bring disputes and issues that may result in disputes (including without limitation any asserted occurrence of a material breach by a Party) to the attention of the Committee in a timely manner, and function as the point of first referral in all matters of conflict resolution;

(b) provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties;

(c) plan and coordinate cooperative efforts, internal communications, and external communications between the Parties with respect to this Agreement; and

(d) take responsibility for ensuring that meetings and the production of meeting agendas and minutes occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

2.5 **Exchange of Information**. Within *** following the Effective Date and on an ***, ModeX shall disclose to Merck all ModeX Know-How related to the Research Program. Promptly following the completion of the Research Program, and thereafter from time to time upon Merck's reasonable request and with the oversight of the Committee (if not then-disbanded), ***, ModeX shall disclose to Merck (or Merck's chosen contract manufacturing organization or CDMO) in English and in writing or in an electronic format all ModeX Know-How that was not previously disclosed (including ***) in ***. Such information transfer shall include, to the extent not already provided, any information contemplated in the initial technology transfer provided in the Research Plan. ModeX shall provide Merck with all reasonable assistance required in order to transfer to Merck the ModeX Know-How, Joint Information and Inventions, and other information required to be produced pursuant to this Section 2.5, in each case, in a timely manner. The support described in this Section 2.5 shall be provided by ***. ***.

2.6 **Records and Reports**.

2.6.1 **Records**. ModeX shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved in the performance of the Research Program by ModeX.

2.6.2 **Copies and Inspection of Records**. Merck shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such records of the ModeX referred to in Section 2.6.1. ModeX shall maintain such records and the information disclosed therein in confidence in accordance with Section 4.1. Merck shall have the right to arrange for its employee(s) or consultant(s) involved in the activities contemplated hereunder to visit the offices and laboratories of ModeX and any of its Third Party sublicensees or contractors as permitted under Section 2.2 during normal business hours and upon reasonable notice, and to discuss the Research Program work and its results in detail with the technical personnel and consultant(s) of Merck; provided that Merck's exercise of such right shall be consistent with Merck's ordinary course business practices for audit of its own third party contractors. Upon Merck's reasonable request and subject to the confidentiality and nonuse obligations herein, ModeX shall provide copies of the records described in Section 2.6.1.

2.7 **Research Information and Inventions**.

2.7.1 The entire right, title, and interest in:

(a) ModeX Information and Inventions shall be owned solely by ModeX;

(b) Merck Information and Inventions shall be owned solely by Merck; and

(c) Joint Information and Inventions shall be owned jointly by ModeX and Merck.

2.7.2 Each Party shall *** disclose to the other Party in writing the development, making, conception, or reduction to practice of ModeX Information and Inventions, ***, and Joint Information and Inventions. For the purposes of determining ownership under this Section 2.7, inventorship shall be determined in accordance with United States patent laws (regardless of where the applicable activities occurred). Subject to the licenses granted to the other Party under this Agreement and the other terms and conditions of this Agreement, each Party shall have ***; provided, that ***; provided, further, that, in the event that ***.

2.8 **Research Term; Filing of IND**.

2.8.1 Except as otherwise provided in this Agreement, the term of the Research Program shall commence on the Effective Date and continue until *** (the "**Research Term**").

2.8.2 At any time during the Research Term, Merck may, in its sole discretion and upon *** days' written notice to ModeX, elect to transfer the remaining activities under the Research Plan to Merck, in which case, upon completion of the Know-How transfer contemplated by Section 2.5, ModeX's obligations with respect to such Research Program under the Research Plan shall terminate.

2.8.3 Upon the earliest of (a) the transfer of the Research Program to Merck in accordance with Section 2.8.2 and (b) conclusion of the Research Term, Merck shall be solely responsible for all further Development and Commercialization of Vaccines and Products, in accordance with the terms and conditions of this Agreement, including Article 3.

2.9 **Exclusivity**.

2.9.1 **ModeX Exclusive Efforts**. During the Term, and subject to Section 2.9.2, *** other than in the conduct of activities under this Agreement (including the Research Program), ***, or *** to conduct any of the foregoing activities, other *** under this Agreement.

2.9.2 **Exclusion:** ***. Notwithstanding anything to the contrary in this Agreement, ***, in each case, whether ***: (x) a ***; or (y) a *** on the *** following such acquisition, provided that:

(a) upon such ***, and the ***; and

(b) ModeX *** (which may be by way of an ***) and uses ***.

(c) For clarity, the ***.

2.10 **Compliance with Law and Ethical Business Practices**.

2.10.1 *** shall perform its obligations under this Agreement, including in the conduct the Research Program, in accordance with Applicable Law, including (where applicable) Good Laboratory Practices. *** shall notify the other in writing of any deviations from Applicable Law ***. *** hereby certifies that it has not and will not employ or otherwise use in any capacity the services of any person or entity debarred under Section 21 U.S.C. § 335a in performing any services hereunder. *** shall notify the other in writing immediately if any such debarment occurs or comes to its attention, and shall promptly remove any person or entity so disbarred from performing any activities under this Agreement (for instance, under the Research Program, or function or capacity related to a Vaccine or Product). *** shall have the right, in its sole discretion, to terminate this Agreement immediately in the event that the *** fails to promptly remove any such persons.

2.10.2 ModeX acknowledges that Merck's corporate policy requires that Merck's business must be conducted within the letter and spirit of the law. By signing this Agreement, ModeX agrees to conduct the services contemplated herein in a manner which is consistent with both Applicable Law and good business ethics.

2.10.3 Specifically, ModeX represents and warrants that none of its employees, agents, officers, or other members of its management are officials, officers, agents, representatives of any government or public international organization (as defined in the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1). *** shall make any payment, either directly or indirectly, of money or other assets, including any compensation derived from or in connection with this Agreement (hereinafter collectively referred as a "**Payment**"), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively referred as "**Officials**") where such Payment would constitute violation of any Applicable Law. In addition, regardless of legality, *** shall make any Payment either

directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of the *** business.

2.10.4 No employee of Merck or its Affiliates shall have authority to give any direction, either written or oral, relating to the making of any commitment by ModeX or its agents to any Third Party in violation of terms of this or any other provisions of this Agreement.

2.10.5 ModeX certifies to Merck that as of the date of this Agreement, ModeX has screened itself, and its officers, directors and employees against the Exclusions Lists and that it has informed the Merck whether ModeX, or any of its officers or directors has been in Violation. After the execution of this Agreement, ModeX shall notify Merck in writing immediately if any such Violation occurs and comes to its attention.

2.10.6 A failure of a Party to abide by the provisions of this Section 2.10 shall be deemed a material breach of this Agreement. The other Party may, in such case, terminate this Agreement subject to and in accordance with Section 8.3(a), at its sole discretion without prejudice to any other remedies that may be available to such Party.

2.11 **Animal Research**. If animals are used in research hereunder, ModeX will comply with the Animal Welfare Act or any other applicable local, state, national and international laws and regulations relating to the care and use of laboratory animals. Merck encourages ModeX to use the highest standards, such as those set forth in the Guide for the Care and Use of Laboratory Animals (NRC, 1996), for the humane handling, care, and treatment of such research animals. ModeX hereby certifies that it has and shall maintain current and valid accreditation from AAALAC during the Term. Any animals which are used in the course of the Research Program, or products derived from those animals, such as eggs or milk, will not be used for food purposes, nor will these animals be used for commercial breeding purposes.

2.12 **CMC Development and Manufacturing**. The allocation of responsibilities with respect to CMC Development activities and the Manufacture of Product and Vaccine for use in connection with the Research Program shall be as set forth in the Research Plan. The Party responsible for such CMC Development and Manufacturing (the "**Manufacturing Party**") (as set forth in the Research Plan) will use a Third-Party contract development and manufacturing organization ("**CDMO**") to carry out such activities unless otherwise agreed by the Committee. All ***. For instance, if *** for the *** activities contemplated under the Research Plan (for clarity, ***). Upon *** request, *** to (a) facilitate ***; (b) ensure compliance with Applicable Laws and ***, in accordance with the Research Plan; and (c) include in any agreement with the *** and a requirement that the ***, resolve any adverse audit findings to the reasonable satisfaction of ***. If *** in accordance with Section 2.8.2, then, upon *** request, *** (or ***) in a timely manner following such election. Following the Research Term (or earlier transfer of the Research Program under Section 2.8.2) Merck will be solely responsible for the Manufacture of Vaccines and Products, at *** expense.

ARTICLE 3
LICENSES; DEVELOPMENT AND COMMERCIALIZATION

3.1 **License Grants to Merck**.

3.1.1 **Grant of License**. ModeX hereby grants to Merck, during the Term, an exclusive (even as to ModeX, subject to Section 3.1.2), sublicensable (in accordance with Section 3.5), royalty-bearing license under the Licensed Intellectual Property, to (i) conduct research under the Research Program and fulfill Merck's obligations under the Research Plan, and (ii) Develop, Manufacture, use and Commercialize Vaccines and Products in the Field in the Territory.

3.1.2 **ModeX Retained Rights**. Notwithstanding the scope of the exclusive license granted to Merck under Section 3.1.1, subject to the terms and conditions of this Agreement, during the Research Term, ModeX shall retain rights under the Licensed Intellectual Property for the sole purpose of performing ModeX's obligations under the Research Plan in accordance with this Agreement.

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**. Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any Information disclosed to it under this Agreement or under any Know-How or Patent Rights owned or Controlled by the other Party or its Affiliates.

3.4 **No Grant of Inconsistent Rights by ModeX**. ModeX (and its Affiliates) shall not assign, transfer, convey or otherwise grant to any Affiliate or Third Party or otherwise encumber (including through lien, charge, security interest, mortgage, encumbrance or otherwise, except pursuant to this Agreement) (a) any rights to any Licensed Intellectual Property (or any rights to any intellectual property that would otherwise be included in the Licensed Intellectual Property), in any manner that conflicts with the grant of the rights to or licenses under Licensed Intellectual Property to Merck hereunder, or (b) any rights to any Vaccine or Product (provided that ModeX shall grant to Merck the rights to the Vaccine and Product as set forth herein).

3.5 **Sublicenses**. Merck shall have the right to sublicense (through multiple tiers of sublicenses) any or all of the licenses granted to Merck hereunder. In the case of ***, Merck may sublicense such licenses ***; provided, however, that ***: (a) ***; (b) to any ***; or (c) in connection with the ***. Merck shall be responsible for ensuring that the performance by any of its sublicensees hereunder that are exercising rights under a sublicense hereunder is in accordance with the applicable terms of this Agreement as if such performance was by Merck, and the grant of any such sublicense shall not relieve Merck of its obligations under this Agreement (except to the extent they are performed by any such sublicensee(s) in accordance with this Agreement). Any sublicense granted by Merck hereunder shall be pursuant to a written agreement that: (i) is consistent with the terms of this Agreement, including intellectual property terms and confidentiality, non-disclosure, and non-use provisions at least as restrictive or protective of the Parties as those set forth in this Agreement; and (ii) otherwise includes terms sufficient to enable Merck to comply with its obligations under this Agreement, for example a *** under this Agreement. *** with this Agreement.

3.6 **Development and Commercialization**. Following the conclusion of the Research Term, ***, in each of (a) ***.

3.7 **Excused Performance**. In addition to the provisions of Article 6, ***, in ***, such condition or event exists. *** determination of *** shall be made in accordance with *** for determining if a ***. Upon request, *** with reasonable supporting materials (excluding, however, ***) following ***.

3.8 **Regulatory Matters**. In the event that Merck determines that any regulatory filings for any Vaccines or Products are required for any activities hereunder (including any activities under the Research Program), including INDs, NDAs and other Marketing Authorizations (as applicable), then as between the Parties, *** shall: (a) have the *** to obtain such regulatory filings in its (or its Related

Party's) name and (b) be the ***. As between the Parties, *** shall have the *** with respect to the Vaccines or Products, including during the Research Term. For clarity, during the Term, *** with respect to the Vaccines or Products.

ARTICLE 4
CONFIDENTIALITY AND PUBLICATION

4.1 **Nondisclosure Obligation**. All Information disclosed by one Party to the other Party hereunder shall be maintained in confidence by the receiving Party and shall not be disclosed to any Third Party or used for any purpose except as set forth herein without the prior written consent of the disclosing Party, except to the extent that such Information:

4.1.1 is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;

4.1.2 is in the public domain by use or publication before its receipt from the disclosing Party, or thereafter enters the public domain through no fault of the receiving Party;

4.1.3 is subsequently disclosed to the receiving Party by a Third Party who may lawfully do so and is not under an obligation of confidentiality to the disclosing Party; or

4.1.4 is developed by the receiving Party independently of Information received from the disclosing Party, as documented by the receiving Party's business records.

Any combination of features or disclosures shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.

4.2 **Permitted Disclosures**. Subject to the exclusions in Section 4.1.1-4.4.4, the receiving Party may only use and disclose the disclosing Party's Information as follows:

4.2.1 where the Information is disclosed to governmental or other regulatory agencies in order to obtain Patents Rights or to gain or maintain approval to conduct Clinical Trials or Marketing Authorization, but such disclosure shall be only to the extent reasonably necessary to obtain Patent Rights or such authorizations; or

4.2.2 where the Information is deemed necessary by:

(a) *** to be disclosed to Related Parties, agent(s), consultant(s), or other Third Parties for purposes of performing *** obligations or exercising *** rights under this Agreement, or (in the case of non-confidential or non-trade secret Information) as *** and its Affiliates may deem necessary or advisable in the ordinary course of business in accordance with this Agreement;

(b) *** to be disclosed to Related Parties, agent(s), consultant(s), upstream licensors, or other Third Parties for purposes of performing *** obligations under this Agreement or any ***;

(c) the receiving Party to be disclosed to such Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the receiving Party; or

(d) the receiving Party to be disclosed in connection with a potential or actual financing (for instance, a ***), in which case such Party shall have the further right to disclose Information to Third Parties involved in such financing; or

(e) the receiving Party to be disclosed in connection with a potential or actual merger or acquisition ***;

in each case (of (a)-(e)), on the condition that such Third Parties agree to be bound by confidentiality and non-use obligations that substantially are no less stringent than those confidentiality and non-use provisions contained in this Agreement; provided, that the term of confidentiality for such Third Parties shall be no less than ten (10) years.

4.3 **Required Disclosures**. If a Party is required by judicial or administrative process (including a request for discovery received in an arbitration or litigation proceeding) or by Applicable Law (*e.g.*, securities laws, rules, and regulations) to disclose Information that is subject to the non-disclosure provisions of this Section 4.1 or Section 4.4, such Party shall promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations. Information that is disclosed by judicial or administrative process shall remain otherwise subject to the confidentiality and non-use provisions of this Section 4.1 and Section 4.4, and the Party disclosing confidential Information pursuant to law or court order shall take all steps reasonably necessary, including obtaining an order of confidentiality, to ensure the continued confidential treatment of such Information, and disclosing only the minimum amount required by such judicial or administrative process. The Parties will consult and cooperate fully with each other on the provisions of this Agreement to be redacted in any filings made by the Parties with the Securities and Exchange Commission or similar governmental agency in the U.S. or abroad, or as otherwise required by Applicable Law.

4.4 **ModeX Know-How**. To the extent there is any ModeX Know-How ***, ModeX agrees to treat any such ModeX Know-How in accordance with Section 4.1, subject to Section 4.1.2 and Section 4.2. All information relating specifically ***.

4.5 **Publication**.

4.5.1 **Research Program Results**. Each Party recognizes that the publication or disclosure of papers, presentations, abstracts or any other written or oral presentations regarding results of and other information regarding the Research Program, may be beneficial to both Parties. Each Party also recognizes the mutual interest in obtaining valid patent protection and in protecting business interests and trade secret information. Accordingly, except for disclosures permitted pursuant to Section 4.1, Section 4.2, or Section 4.3, either Party, its employee(s) or consultant(s) wishing to make a publication relating to the ***. The disclosing Party shall comply with any such requests of the reviewing Party.

4.5.2 **Other Publications**. Other than with respect to Research Program results, as set forth in Section 4.5.1, ModeX shall have no right to make any publication relating to any Vaccine or Product without the prior written consent of Merck (which Merck may withhold in its sole discretion), and subject to the remainder of this Article 4, Merck shall have the right to make publications relating to Vaccines or Products in its sole discretion.

4.6 **Publicity and Use of Names**. The Parties have mutually agreed on the press release with respect to this Agreement, a copy of which is set forth in Schedule 4.6. Either Party may make public disclosures that are limited to the specific contents of such press release. Except as otherwise expressly set forth herein, no disclosure of the existence, or the terms, of this Agreement may be made by either Party, and no Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by Applicable Law. Any such disclosure required by Applicable Law shall be subject to Section 4.3.

4.7 **Prior Non-Disclosure Agreements**. As of the Effective Date, the terms of this Article 4 shall supersede any previous nondisclosure agreement entered into between the Parties or Affiliates of the Parties (the "**Prior Non-Disclosure Agreement**"). Any information disclosed pursuant to such Prior Non-Disclosure Agreement shall be deemed to have been disclosed pursuant to this Agreement.

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 [***]

ARTICLE 5
PAYMENTS; ROYALTIES AND REPORTS

5.1 **Upfront Payment**. In consideration for the rights granted to Merck under this Agreement, Merck will pay to ModeX within *** after the Effective Date, a one-time, irrevocable, non-refundable upfront payment of Fifty Million U.S. Dollars ($50,000,000.00).

5.2 **Milestone Payments**.

5.2.1 **Development Milestone Payments**. Subject to the terms and conditions of this Agreement, Merck shall pay to ModeX the following one-time milestone payments (the "**Development Milestone Payments**"), for the first achievement of the following milestone events by a Vaccine or Product, as applicable (the "**Development Milestone Event**"), during the Term:

Development Milestone Event	Development Milestone Payment			
	First Indication	Second Indication	Third Indication	Fourth Indication
***	$***	---	---	---
***	$***	$***	$***	$***
***	$***	$***	$***	$***
***	$***	$***	$***	$***
***	$***	$***	$***	$***
***	$***	$***	$***	$***

5.2.2 **Commercial Milestone Payments**. On a *** basis, Merck shall pay to ModeX the following one-time milestone payments (the "**Commercial Milestone Payments**") with respect to the first Calendar Year during which aggregate annual Net Sales of a *** in the Territory exceed the corresponding threshold (each, a "**Commercial Milestone Event**"):

Aggregate Annual Net Sales in the Territory of a Product (Commercial Milestone Event)	Commercial Milestone Payment
$***	$***
$***	$***
$***	$***

5.2.3 **General Milestone Payment Provisions**.

(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 calculated based on aggregate worldwide Net Sales of each Product, provided that the determination of whether the royalty shall be calculated using the *** rate under Section 5.3.1(b) shall be determined on a country-by-country basis.

(d) Royalty Period. Royalties on each Product at the rates set forth above shall continue on a country-by-country basis until the *** of: (i) ***; or (iii) *** (the "**Royalty Period**").

(e) All royalties are subject to the following conditions:

(i) only one royalty shall be due with respect to the same unit of Product;

(ii) no royalties shall be due upon the ***, but in such cases the royalty shall be due and calculated upon *** to the first independent Third Party;

(iii) no royalties shall accrue on *** of Product by Merck or its Related Parties ***; and

(iv) no royalties shall accrue on the *** or ***.

5.3.2 **Royalties for Bulk Vaccine**. In those cases in which Merck sells bulk Vaccine rather than Product in packaged form to an independent Third Party, the Net Sales (and therefore royalty obligations of this Section 5.3) shall be determined ***.

5.3.3 **Compulsory Licenses**. If a compulsory license is granted to a Third Party with respect to Vaccine or Product in any country in the Territory with a *** by Section 5.3.1, then the royalty rate to be paid by Merck on Net Sales by or to such Third Party in that country under Section 5.3.1 shall be ***.

5.3.4 **Third-Party Licenses**. ***, in the event that Merck obtains (on or after the Effective Date) a license under, or other rights to, Patent Rights from any Third Party(ies) that are necessary *** in order to Develop, Manufacture, or Commercialize Vaccine(s), or Product(s) (hereinafter "**Third-Party Licenses**"), *** of *** under such Third-Party Licenses by Merck or its Related Parties *** for a Calendar Quarter *** with respect to the sale of such Product in such Calendar Quarter; provided, that if *** is not able to *** then ***. At the request of *** in (a) obtaining *** or (b) otherwise *** that may be necessary in order to ***. *** the Parties acknowledge that *** has entered into or intends to enter into, concurrently with this Agreement, the ***, and that the *** constitutes a Third-Party License hereunder. In the event that *** with rights to the patent rights included within the *** after the date hereof, covering the same ***, for any indication within the field of use described in ***, the Parties further acknowledge and agree that *** for any purpose under this Agreement, unless otherwise agreed by the Parties in writing.

5.3.5 ***.

(a) Notwithstanding the ***.

(b) Notwithstanding anything to the contrary in this Agreement ***. Merck shall include the amount of any such *** in the Net Sales Report for the *** with the *** in such subsequent ***.

(c) Any *** that is not available to *** may be ***.

5.4 **Net Sales Reports; Payment of Royalty**. During the Term, following the First Commercial Sale of a Product, Merck shall furnish to ModeX a written report (the "**Net Sales Report**") for the Calendar Quarter showing the Net Sales of all Products subject to royalty payments or Commercial Milestone Payments sold by Merck and its Related Parties in the Territory during the reporting period and Calendar Year-to-date, and the royalties payable and the Commercial Milestone Payments payable under this Agreement. Net Sales Reports shall be due on the *** day following the close of each Calendar Quarter. Royalties and Commercial Milestone Payments shown to have accrued by each Net Sales Report shall be due and payable on ***. Merck shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined. Such Net Sales Reports must also include (a) the ***.

5.5 **Audits**.

5.5.1 Upon the written request of ModeX and not more than *** in each ***, Merck shall permit an independent certified public accounting firm of nationally recognized standing selected by

ModeX and reasonably acceptable to Merck, at *** expense (subject to the last sentence of Section 5.5.2), to have access during normal business hours to such of the records of Merck as may be reasonably necessary to verify the accuracy of any payments owed hereunder or information contained in the Net Sales Reports hereunder, in each case for any *** ending not more than *** prior to the date of such request. The accounting firm shall disclose to ModeX only the amounts which such accounting firm *** (*e.g.*, whether the Net Sales Reports are ***). No other information shall be provided to ModeX.

5.5.2 If such accounting firm correctly identifies a discrepancy made during such period, the appropriate *** of the date ModeX delivers to Merck such accounting firm's written report so correctly concluding, or as otherwise agreed upon by the Parties. The *** by such accounting firm shall be ***; provided, that if such audit *** that *** of the total royalties owed, then the ***.

5.5.3 Merck shall include in each sublicense granted by it pursuant to this Agreement a provision *** to the same extent required of Merck under this Agreement.

5.5.4 ModeX shall treat all financial information subject to review under this Section 5.5 or under any sublicense agreement in accordance with the confidentiality and non-use provisions of this Agreement, and shall cause its accounting firm to enter into a customary and reasonably acceptable confidentiality agreement with Merck obligating it to retain all such information in confidence pursuant to such confidentiality agreement.

5.5.5 In the event that ModeX requests reimbursement of royalties pursuant to Section 5.3.5(b), Merck shall be entitled to audit the records of ModeX as necessary to verify the amount of any royalty reimbursement requested by ModeX as provided under this Section 5.5, *mutatis mutandis*.

5.6 **Payment Exchange Rate**. All payments to be made by Merck to ModeX under this Agreement shall be made in United States dollars and may be paid by check made to the order of ModeX or bank wire transfer in immediately available funds to such bank account in the United States as may be designated in writing by ModeX from time to time. In the case of sales outside the United States, the rate of exchange to be used in computing the monthly amount of currency in equivalent United States dollars due ModeX shall be made at the monthly rate of exchange utilized by Merck in the ordinary course of business (in accordance with Merck's Accounting Standards) at the time such exchange is to be calculated.

5.7 **Tax Withholding**. ModeX shall be liable for all income and other taxes (including interest) ("**Taxes**") imposed upon any payments made by Merck to ModeX under this Article 5. If Applicable Law requires the withholding of any Taxes, Merck shall make such withholding payments and shall subtract the amount thereof from the amounts otherwise owed under this Agreement. ***.

5.8 **Income Tax Withholding Due to Sublicenses**. If, solely as a result of Merck's sublicense of rights under this Agreement, the sublicensee is required to withhold Taxes on any payments to ModeX under this Article 5 which would not have been imposed in the absence of such sublicense, ***such that ***. This Section 5.8 shall be applied ***.

5.9 **Payments**. Merck shall submit to ModeX appropriate proof of payment of the withheld taxes as well as the official receipts within a ***. Merck shall provide ModeX reasonable assistance in order to allow ModeX to obtain the benefit of any present or future treaty against double taxation which may apply to payments made by Merck to ModeX under this Article 5.

5.10 **Interest on Late Payments**. If any payment due under this Agreement is not paid in when due, then interest thereon and on any unpaid accrued interest (before and after any judgment) shall accrue at an ***, such interest to run from ***.

ARTICLE 6
REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION

6.1 **Representations and Warranties of Each Party and OPKO**. ModeX and OPKO each hereby represents and warrants to Merck, and Merck hereby represents and warrants to ModeX and OPKO that, as of the Effective Date:

6.1.1 such Person is duly organized and validly existing under the laws of the state or jurisdiction of its organization and has full corporate right, power, and authority to enter into this Agreement and to perform its obligations hereunder;

6.1.2 the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby have been duly authorized by the necessary corporate actions of such Person. This Agreement has been duly executed by such Person. This Agreement and any other documents contemplated hereby constitute valid and legally binding obligations of such Person enforceable against it in accordance with their respective terms, except to the extent that enforcement of the rights and remedies created thereby is subject to bankruptcy, insolvency, reorganization, moratorium and other similar laws of general application affecting the rights and remedies of creditors; and

6.1.3 the execution, delivery and performance by such Person of this Agreement and any other agreements and instruments contemplated hereunder will not (a) in any respect violate any statute, regulation, judgment, order, decree or other restriction of any governmental authority to which such Person is subject, (b) violate any provision of the corporate charter, by-laws or other organizational documents of such Person, or (c) constitute a material violation or breach by such Person of any provision of any material contract, agreement or instrument to which such Person is a party or to which such Person may be subject although not a party.

6.2 **ModeX Representations and Warranties**. Except as set forth in the disclosure schedule in **Schedule 6.2** (with specific reference to the section or subsection of this Agreement to which the information stated in such disclosure schedule relates), ModeX represents and warrants (or as applicable covenants) to Merck that, as of the Effective Date:

6.2.1 all issued Patent Rights within the ModeX Patent Rights are in full force and effect, and, to ***;

6.2.2 it has the full right, power and authority to enter into this Agreement, to perform the activities hereunder, including the Research Program, and to grant the licenses granted hereunder (including under Article 3);

6.2.3 it has not *** that would conflict with the rights granted to Merck hereunder;

6.2.4 no ***;

6.2.5 neither ***;

6.2.6 other than the ***;

6.2.7 to the best of ModeX's knowledge, ***;

6.2.8 there are no claims, judgments, or settlements against or owed by ModeX (or any of its Affiliates), and there are no pending or threatened (in writing) claims or litigation, in each case relating to the ModeX Patent Rights or ModeX Know-How;

6.2.9 to the best of ModeX's knowledge, (a) ModeX has disclosed to Merck all reasonably relevant information requested by Merck ***;

6.2.10 neither ModeX nor any of its Affiliates has received any written notification from a Third Party that the Development, Manufacture, use, or Commercialization of Vaccines or Products infringes or misappropriates the Patent Rights or Know-How owned or controlled by such Third Party, and ModeX has no knowledge that a Third Party has any basis for any such claim;

6.2.11 ModeX has complied with all existing country-specific Applicable Laws involving inventor remuneration associated with the ModeX Patent Rights owned by ModeX, including, if applicable, Article 6 of the Third Amendment of Chinese Patent Law;

6.2.12 to the best of ModeX's knowledge, Schedule 1.77 sets forth a true, correct, and complete list of ModeX Patent Rights existing as of the Effective Date, and such schedule contains all application numbers and filing dates, registration numbers and dates, jurisdictions and owners. The ModeX Patent Rights and ModeX Know-How constitute all intellectual property owned or otherwise Controlled (through license or otherwise) by ModeX (or any of its Affiliates) that are necessary or useful for (or otherwise used by ModeX or any of its Affiliates in connection with) the Vaccines and the Products or the Development, Manufacture, Commercialization or use thereof;

6.2.13 to the best of ModeX's knowledge, ModeX has disclosed to Merck all material information and data and all material correspondences to or from any Regulatory Authority, in each case related to the Research Program, or any Vaccines or Products, regardless of whether such data and information would have a positive, negative or neutral impact on the potential commercial, scientific or strategic value or attractiveness of the Research Programs, or any Vaccine or Product;

6.2.14 ModeX has obtained all necessary consents, approvals, and authorizations of all governmental authorities required to be obtained by it in connection with the execution, delivery, and performance of this Agreement;

6.2.15 except for the ModeX Third-Party License Agreements set forth on Schedule 1.81, neither ModeX nor any of its Affiliates is party to any ***;

6.2.16 neither ModeX nor any of its Affiliates has obtained, or filed for, any INDs, NDAs or Marketing Authorizations for any ***;

6.2.17 ModeX (and its Affiliates) has not employed or otherwise used in any capacity the services of any Person debarred under Applicable Law, including under 21 U.S.C. § 335a or any foreign equivalent thereof, with respect to any Vaccine or Product or otherwise in performing any research or other Development with respect thereto;

6.2.18 all Development (including non-clinical studies and Clinical Trials) related to the Vaccines or Products has been conducted in accordance with all Applicable Laws; and

6.2.19 other than the ModeX Third-Party License Agreements set forth on Schedule 1.81, there are no agreements (including any licenses), written or oral, granting any licenses or other rights to (or from) ModeX (or any of its Affiliates) relating to the Vaccines, or Products or the ModeX Know-How or ModeX Patent Rights that conflict with the licenses or other rights granted by ModeX hereunder.

6.3 **ModeX Third-Party License Agreements**.

6.3.1 **Representations, Warranties, and Covenants**. ModeX represents and warrants to Merck that (x) it has provided to Merck as of the Effective Date a copy of each of the ModeX Third-Party License Agreements, and each such copy includes a copy of any and all amendments, restatements, side letters, and other modifications thereto, as each such ModeX Third-Party License Agreement is in effect as of the Effective Date, and (y) each such copy is true, complete, and correct in all respects except that certain financial terms or terms unrelated to the licenses granted to Merck hereunder, in each case which do not diminish Merck's rights or expand Merck's obligations under this Agreement, have been redacted. ModeX further covenants and agrees that during the Term, ***, (a) ModeX shall: (i) satisfy all of its

obligations under (including making all payments), and (ii) *** take all steps to maintain in full force and effect, each of the ModeX Third-Party License Agreements as they may relate to the Licensed Intellectual Property or any Product or Vaccine; (b) it will not assign (except an assignment to a party to which this Agreement has been assigned as permitted under Section 9.2), amend, restate, amend and restate, terminate in whole or in part, or otherwise modify any of the ModeX Third-Party License Agreements without the prior written consent of Merck (not to be unreasonably delayed), ***; (c) it will provide Merck with prompt notice of any claim of a breach under any of the ModeX Third-Party License Agreements or notice of termination of any of the ModeX Third-Party License Agreements, made by either ModeX or the counterparty to such ModeX Third-Party License Agreement (or any party acting on behalf of such counterparty); and (d) it will promptly send to Merck copies of all other material correspondence to or from the counterparty to such ModeX Third-Party License Agreement related to such ModeX Third-Party License Agreement ***. Any breach of this Section 6.1.3 by ModeX shall constitute a material breach of this Agreement.

6.3.2 **Certain Terms of ModeX Third-Party License Agreements**. To the extent that the ***. With limiting the foregoing, *** shall be responsible for all of the *** under any of the ***, including any and all ***.

6.4 **Disclaimer**. Except as otherwise expressly set forth in this Agreement, ***.

6.5 **Indemnification**.

6.5.1 **Indemnification by ModeX**. ModeX shall indemnify, defend, and hold harmless Merck, its Affiliates, and its and their respective directors, officers, employees, contractors, and agents, and their respective successors and assigns (collectively, the "**Merck Indemnified Parties**") from any and all Third-Party claims, actions, causes of action, liabilities, losses, damages, costs or expenses, including reasonable attorneys' fees, which directly or indirectly arise out of or relate to (a) a breach by ModeX of this Agreement, including any representation or warranty made by ModeX or OPKO in this Agreement; (b) the *** of, or violation of Applicable Law by, a ModeX Indemnified Party in connection with this Agreement; or (c) ***; in each case (of (a)-(b)) excluding to the extent arising out of or relating to (i) a breach by Merck of this Agreement; or (ii) the *** of, or violation of Applicable Law by, a Merck Indemnified Party.

6.5.2 **Indemnification by Merck**. Merck shall indemnify, defend, and hold harmless ModeX, its Affiliates, and its and their respective directors, officers, licensors, employees, contractors, and agents, and their respective successors and assigns (collectively, the "**ModeX Indemnified Parties**") from any and all Third-Party claims, actions, causes of action, liabilities, losses, damages, costs or expenses, including reasonable attorneys' fees, which directly or indirectly arise out of or relate to (a) a breach by Merck of this Agreement, including any representation or warranty made by Merck in this Agreement; (b) the *** of, or violation of Applicable Law by, a Merck Indemnified Party in connection with this Agreement; or (c) ***; in each case (of (a)-(c)) excluding to the extent arising out of or relating to (i) a breach by ModeX of this Agreement; (ii) the *** of, or violation of Applicable Law by, a ModeX Indemnified Party; or (iii) the ***.

6.5.3 **Indemnification Procedure**. If a Party is seeking indemnification under Section 6.5.1 or 6.5.2, (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the claim giving rise to the obligation to indemnify pursuant to Section 6.5.1 or 6.5.2, as applicable as soon as reasonably practicable after receiving notice of the claim (provided, however, any delay or failure to provide such notice shall not constitute a waiver or release of, or otherwise limit, the Indemnified Party's rights to indemnification under Section 6.5.1 or 6.5.2, as applicable except to the extent that such delay or failure materially prejudices the Indemnifying Party's ability to defend against the relevant claims). The Indemnifying Party shall have the right to assume the defense of any such claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party. Neither Party shall settle any claim without the prior written consent of the other

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 ***. ***.

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, together with notice of its filing date and serial number. ModeX shall promptly give notice to Merck of the abandonment of any ModeX Patent Rights claiming ModeX Information and Inventions for which ModeX has the first right for filing.

(b) Prosecution and Maintenance of ModeX Product Patent Rights. *** Merck shall control the filing, prosecution, and maintenance of any ModeX Patent Rights *** and the Exempted Licensed Patent (as defined under the Sanofi In-License Agreement) (collectively, the "**ModeX Product Patent Rights**") in the Territory using ***. *** the opportunity to review substantive office action responses before filing, and shall ***, but will have ***.

(c) Prosecution and Maintenance of Sanofi Patents. Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge that the filing, prosecution, and maintenance of the Sanofi Patents ***. As between the Parties *** with respect to the filing, prosecution, and maintenance of the Exempted Licensed Patent.

(d) Prosecution and Maintenance of Other ModeX Patent Rights. Subject to Section 7.1.1(a), Merck and ModeX *** of any ModeX Patent Rights other than the ModeX Product Patent Rights using mutually agreeable outside counsel. *** associated with such filing, prosecution, and maintenance of such ModeX Patent Rights. If there is a disagreement between the Parties regarding prosecution strategy for such ModeX Patent Rights and *** shall have the final decision-making authority.

(e) Option of Merck to File, Prosecute and Maintain ModeX Patent Rights. On a country-by-country basis in the Territory, ModeX shall give notice to Merck of any desire to not file patent applications claiming ModeX Information and Inventions or to cease prosecution or maintenance of ModeX Patent Rights and, in such cases, shall permit Merck, in its sole discretion, to (on a country-by-country basis) file such patent applications or to continue prosecution or maintenance of such ModeX Patent Rights ***. In such events, if Merck elects to file patent applications claiming ModeX Information and Inventions, or to continue prosecution or maintenance of ModeX Patent Rights, ModeX shall execute such documents and perform such acts as may be reasonably necessary for Merck to perform such filing, prosecution, or maintenance, and Merck shall control the filing and prosecution and maintenance of such Patent Rights in such country(ies). Any such Patent Rights which are filed, prosecuted, and maintained by Merck ***.

(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 to ModeX Patent Rights and Joint Patent Rights. In the event that elections with respect to obtaining such patent term extensions are to be made, *** Merck shall have the right to make the election and ModeX agrees to abide by such election.

7.1.5 **Other Cooperation**. The Parties agree to cooperate fully and provide any information and assistance that either may reasonably request for the filing, prosecution and maintenance of ModeX Patent Rights and Joint Patent Rights. The Party with the first right to file, prosecute, or maintain Patent Rights under this Section 7.1 will provide any notice of any desire to cease prosecution or maintenance sufficiently in advance of any filing or payment due date, or any other due date that requires action in order to avoid loss of rights. The Parties further agree to take reasonable actions to ***.

7.1.6 **Filing, Prosecution and Maintenance Expenses**. Subject to Section 7.1.1(c), with respect to all filing, prosecution and maintenance activities under this Section 7.1, the *** related to such activities.

7.1.7 **Inventor Remuneration**. ModeX shall comply with all applicable country-specific inventor remuneration laws and regulations, including Article 6 of the Third Amendment of Chinese Patent Law associated with ModeX Patent Rights and Joint Patent Rights, when inventor remuneration obligations are triggered by an employee of ModeX or its Affiliates, or a Third Party acting on behalf of ModeX or its Affiliates.

7.2 **Interference, Derivation, Opposition, Reexamination, Reissue, Supplemental Examination, *Inter Partes* Review and Post-Grant Review Proceedings**.

7.2.1 **Third Party Initiated Proceedings**. Each Party shall, within *** of learning of such event, inform the other Party of any request for, or filing or declaration of, any interference, derivation proceeding, opposition, reexamination requested by a Third Party, *inter partes* review, post-grant review

or similar contested administrative proceeding involving a Third Party relating to ModeX Patent Rights or Joint Patent Rights. Merck and ModeX shall thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. ***, Merck shall have the first right to control such proceedings with respect to ModeX Patent Rights and Joint Patent Rights, and ***.

7.2.2 **Party Initiated Proceedings**. *** Merck shall have the first right to initiate a reexamination, supplemental examination, reissue, or similar administrative proceeding relating to ModeX Patent Rights or Joint Patent Rights. Notwithstanding the foregoing, Merck ***. ModeX shall *** If there is disagreement regarding whether a reexamination, supplemental examination, reissue, or similar administrative proceeding relating to ModeX Patent Rights or Joint Patent Rights should be initiated, ***. In the event that Merck chooses not to initiate a proceeding under this Section 7.2.2, and upon Merck's written consent, ModeX shall have the right to initiate such proceedings. The initiating Party shall have the first right to control such proceedings.

7.2.3 **Cooperation**. In connection with any administrative proceeding under Section 7.2.1 or 7.2.2, Merck and ModeX shall cooperate fully and provide each other with any information or assistance that either may reasonably request. The Parties shall keep each other informed of developments in any such action or proceeding, including the status of any settlement negotiations and the terms of any offer related thereto. For any proceeding not controlled by Merck, *** of any ModeX Patent Right or Joint Patent Right, or *** of Merck ***.

7.2.4 **Sanofi Patent Rights**. Notwithstanding anything herein to the contrary, Merck acknowledges that its *** with respect to any such proceedings involving the Exempted Licensed Patent.

7.2.5 **Expenses**. The Party *** related thereto.

7.3 **Enforcement and Defense**.

7.3.1 The Parties shall give notice to each other of either (a) any infringement of ModeX Patent Rights or Joint Patent Rights ***, or (b) any misappropriation or misuse of ModeX Know-How (collectively, an "**Infringement**"), that may come to its attention. Merck and ModeX shall thereafter consult and cooperate fully to determine a course of action, including the commencement of legal action by either or both Merck and ModeX, to terminate any such Infringement. As between the Parties, Merck, upon notice to ModeX, shall have the first right to initiate and prosecute such legal action *** and in the name of Merck or ModeX, or to control the defense of any declaratory judgment action relating to any Infringement ***. Each Party shall have the right to be represented by counsel of its own choice.

7.3.2 Merck shall promptly inform ModeX if it elects not to exercise its first right under Section 7.3.1 to initiate and prosecute legal action. *** or elects not to exercise its first right under Section 7.3.1 to initiate and prosecute legal action, ModeX shall have the right to either initiate and prosecute such action or to control the defense of such declaratory judgment action in the name of ModeX and, if necessary, Merck. If ModeX elects to do so, the costs of any agreed-upon course of action to terminate Infringement, including the costs of any legal action commenced or the defense of any declaratory judgment, ***. Each Party shall have the right to be represented by counsel of its own choice.

7.3.3 For any action to terminate any Infringement, in the event that a Party is unable to initiate or prosecute such action solely in its own name, the other Party will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for the Party to initiate litigation to prosecute and maintain such action under this Section 7.3. In connection with any action or potential action, Merck and ModeX will cooperate fully and will provide each other with any information or assistance that either may reasonably request, including *** of the ModeX Patent Rights and Joint Patent Rights. Each Party shall keep the other informed of developments in any action or proceeding. For any proceeding not controlled by Merck, ModeX shall *** of any ModeX Patent Right or Joint Patent Right, or ***. For any proceeding controlled by Merck, Merck ***.

7.3.4 If a Third Party asserts that a Patent Right owned or otherwise controlled by it is infringed by the Products in the Field in the Territory, the Party first made aware of such a claim shall ***. Merck shall have the first right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding ***, using counsel of its own choice. Merck shall also have the first right, but not the obligation, ***, using counsel of its own choice. The non-controlling Party shall cooperate with the controlling Party ***, in any such defense and shall have the right, *** to be represented separately by counsel of its own choice in any such proceeding. The controlling Party with respect to a particular claim also shall have the right to control settlement of such claim. All *** in actions commenced pursuant to this Section 7.3.4 shall be ***.

7.3.5 Any recovery obtained by either or both Merck and ModeX in connection with or as a result of any action contemplated by this Section 7.3 with respect to a ***, whether by settlement or otherwise, shall be shared in order as follows:

(a) the Party which initiated and prosecuted the action ***;

(b) the other Party ***; and

(c) the amount of any recovery ***.

7.3.6 Notwithstanding anything herein to the contrary, *** shall have final decision-making authority with respect to any such proceedings involving the Exempted Licensed Patent.

7.3.7 Notwithstanding anything herein to the contrary, Merck shall have the sole right to enforce and defend the Merck Patent Rights and any patents and patent applications claiming Merck Information and Inventions, and shall be solely entitled to retain any recovery obtained in connection with any such action.

7.3.8 ModeX shall inform Merck of any matter of which it becomes aware concerning the submission of an application to the U.S. Food & Drug Administration under Section 351(k) of the U.S. Public Health Services Act (42 USC 262(k)), or to a similar agency under any similar provisions in a country in the Territory, seeking approval of a biosimilar or interchangeable biological product with regard to which Merck is a reference product sponsor involving ModeX Patent Rights or Joint Patent Rights ("**Biosimilar Application**"). ModeX shall provide Merck with any Biosimilar Application it receives within *** of receipt (***). Notwithstanding the foregoing provisions of this Section 7.3, as between the Parties (and subject to the rights of Sanofi under the Sanofi In-License Agreement, as modified by the Sanofi Letter Agreement with respect to the Sanofi Patents), Merck shall have the sole right, in its discretion, to control any legal action and any activity taken to resolve a dispute with respect to any infringement of ModeX Patent Rights or Joint Patent Rights with respect to any Biosimilar Application, including selection of any patents for listing under 42 U.S.C. §262(l), and ModeX shall have no rights in connection therewith. For any action with respect to any infringement of ModeX Patent Rights or Joint Patent Rights with respect to any Biosimilar Application, in the event that Merck is unable to initiate or prosecute such action solely in its own name, ModeX will join such action voluntarily and will execute and cause its Affiliates to execute all documents necessary for Merck to initiate, prosecute and maintain such action. In connection with any action, ModeX shall cooperate with Merck and provide Merck with information and assistance, at Merck's expense, that Merck may reasonably request, including as defined in Section 7.3.3.

ARTICLE 8
TERM AND TERMINATION

8.1 **Term and Expiration**. This Agreement shall be effective as of the Effective Date, and unless terminated earlier pursuant to Section 8.2 or Section 8.3, this Agreement shall continue in full force and effect until one or more Products has received Marketing Authorization and, thereafter, until expiration of all royalty obligations hereunder (the "**Term**"). Upon expiration of this Agreement, Merck's licenses pursuant to Section 3.1 shall become fully paid-up, perpetual licenses.

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 ***.

(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 ***. *** in the manner so described in greater detail in *** shall also:

(i) transfer ***, relating ***; and

(ii) if there are ***.

***.

(g) All *** shall be provided ***. *** shall cooperate and provide reasonable assistance to *** in connection with the ***

(h) ***.

8.4.3 **Additional Effects of Termination by Merck for Material Breach**. If Merck terminates this Agreement under Section 8.3(a), ***, and ModeX shall, within *** days after the effective date of such termination return or cause to be returned to Merck all Information in tangible form, as well as any other material which may have been provided by Merck in any medium in ModeX's or its subcontractors' possession as of the effective date of termination.

8.4.4 **Continuation in Lieu of Termination**. If Merck would be entitled to terminate this Agreement under Section 8.3(a) as a result of an uncured breach that would reasonably be expected to materially diminish the value of the Vaccines, the Products, or the rights granted hereunder with respect to the Vaccines or Products, ***, Merck may, ***, and without limiting any other remedies that may be available to Merck under this Agreement, at law, or in equity, elect to continue this Agreement but may, by notification to ModeX, *** amounts payable under Article 5 (including, for the avoidance of doubt, ***).

8.4.5 **Termination by Merck for Bankruptcy**. If this Agreement is terminated by Merck pursuant to Section 8.3(b) due to the rejection of this Agreement by or on behalf of ModeX under Section 365 of the United States Bankruptcy Code (the "**Code**"), all licenses and rights to licenses granted under or pursuant to this Agreement by ModeX to Merck are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code. The Parties agree that Merck, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against ModeX under the Code, ***. The foregoing provisions of Section 8.4.5 are without prejudice to any rights Merck may have arising under the Code or other Applicable Law.

8.5 **Effect of Expiration or Termination; Survival**. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Any expiration or termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement prior to expiration or termination, including the obligation to pay royalties for Product(s) or Vaccine(s) sold prior to such expiration or termination. The provisions of Article 4 shall survive the expiration or termination of this Agreement and shall continue in effect for ***. In addition, the provisions of ***, shall survive any expiration or termination of this Agreement.

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.

9.2 **Assignment and Change of Control**.

9.2.1 Except as provided in this Section 9.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party.

9.2.2 Merck may, without ModeX's consent, assign this Agreement and its rights and obligations hereunder in whole or in part to a Merck Affiliate or in connection with a Change of Control.

9.2.3 ModeX may, without Merck's consent, assign this Agreement and its rights and obligations hereunder (a) to a ModeX Affiliate or (b) in connection with a Change of Control; provided, that in the case of (b), ModeX must notify Merck within *** Business Days following completion of any such Change of Control, and ***.

9.2.4 In the event of ***, Merck may:

(a) limit its obligations to provide ModeX Net Sales Reports to reporting only Merck's total royalty and Commercial Milestone Payment obligations; provided that, Merck will, if requested by ModeX, provide Net Sales Reports to an independent certified public accounting firm for auditing in accordance with Section 5.5;

(b) terminate and disband the Committee, or limit the matters within its purview in order to reduce the sharing of ModeX Know-How and confidential Information of Merck; or

(c) require ModeX and the Acquiring Entity in the Change of Control transaction to adopt a "firewall" of reasonable safeguards between individuals with access to ModeX Know-How or confidential Information of Merck, on the one hand, and personnel of the Competing Pharma, including in particular any such personnel responsible for the Development, Manufacture, or Commercialization of any Competing Product, on the other hand and ensure that the continued Development or Commercialization by such Competing Pharma of such Competing Product does not make use of or incorporate any technology covered by ModeX Patent Rights or ModeX Know-How licensed to Merck hereunder, and that the Competing Pharma does not have access to any Merck Know-How or any confidential Information of Merck, including for competitive reasons against Merck and its Related Parties and the use of such Patent Rights or Know-How for the development or commercialization of competing products. Subject to the foregoing, the Acquiring Entity may continue to exploit any Competing Product, and ModeX will not be deemed to be in breach of Section 2.9 as a result thereof following the Change of Control.

9.2.5 Any attempted assignment not in accordance with this Section 9.2 shall be void.

9.3 **Parental Guaranty**. OPKO irrevocably and unconditionally, jointly and severally, guarantees (a) the due and punctual payment to Merck, whether stated at maturity, by acceleration or otherwise, of all present and future debts, liabilities and obligations, direct or indirect, absolute or contingent, of ModeX

and its Affiliates to Merck arising pursuant to, in respect of, or in connection with this Agreement, which result from any failure by ModeX or its Affiliates to make timely payments to Merck as required hereunder and (b) performance of, and compliance with, all other obligations of ModeX and its Affiliates under this Agreement (collectively, the "**Guaranteed Obligations**"). The obligations of OPKO under this Section 9.3 shall constitute a present and continuing guarantee of payment and performance and not of collectability, and shall be absolute and unconditional. Without limiting the foregoing, OPKO waives, for the benefit of Merck, (i) ***. This Section 9.3 shall be binding upon, inure to the benefit of, and be enforceable by the successors and permitted assigns of Merck and OPKO.

9.4 **Use of Affiliates**. Each Party shall have the right to exercise its rights and perform its obligations under this Agreement either itself or through any of its Affiliates.

9.5 **Severability**. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein shall not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties shall in such an instance use reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

9.6 **Notices**. All notices which are required or permitted hereunder shall be in writing and sufficient if delivered personally, sent by email (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to ModeX, to:

OPKO Health
4400 Biscayne Boulevard
Miami, FL 33137
Attention: Corporate Secretary
cgreen@opko.com

and:

OPKO Health
Attention: Executive Vice President
srubin@opko.com

if to Merck, to:

Merck Sharp & Dohme LLC
126 East Lincoln Avenue
P.O. Box 2000
Rahway, NJ 07065 USA
Attention: Office of Secretary
Email: office.secretary@merck.com

and:

Merck Sharp & Dohme LLC
126 East Lincoln Avenue
P.O. Box 2000
Rahway, NJ 07065 USA
Attention: Senior Vice President, Business Development

or to such other address(es) as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice shall be deemed to have been given: (a) when delivered if personally delivered or sent by email on a Business Day (or if delivered or sent on a non-

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 of mailing, if sent by registered or certified mail. The Parties hereby agree that, to the extent permitted by Applicable Law, any notice provided in accordance with this Section shall constitute due service of process with respect to any legal proceeding between the Parties arising hereunder and that compliance with the Hague Convention for the Service of Process, if otherwise applicable, shall not be required.

9.7 **Applicable Law**. This Agreement will be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States, without reference to any rules of conflict of laws. The Parties hereby agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement and are strictly excluded.

9.8 **Dispute Resolution**.

9.8.1 Except with respect to an Excluded Claim, the Parties shall negotiate in good faith and use reasonable efforts to settle any dispute, controversy or claim arising from or related to this Agreement or the breach thereof (a "**Dispute**"). Either Party shall give the other Party written notice of any Dispute not resolved in the normal course of business. Within *** days from the date of delivery of such notice, the receiving Party shall submit to the other Party a written response. The notice and response shall include (a) a ***. Within *** days from the date of delivery of the initial notice, the executives of both Parties shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the Dispute. These executives shall have the authority to settle the Dispute and shall be at a higher level of management than the persons with direct responsibility for administration of this Agreement. All negotiations pursuant to this paragraph are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.

9.8.2 If the Parties ***.

9.8.3 For purposes of this Section 9.8, "**Excluded Claim**" shall mean a dispute, controversy or claim that concerns (a) a ***; or (c) ***. Any action concerning Excluded Claims identified in clauses (b) and (c) of this Paragraph may be brought in any court having jurisdiction.

9.9 **Limitation of Liability**. Notwithstanding anything to the contrary contained herein, neither Party shall be liable to the other Party under any theory for any ***, whether arising directly or indirectly out of the transactions contemplated by this Agreement, provided, however, that this limitation shall not limit (a) either Party's liability ***; (b) ***; or (c) ***. To be clear, subject to the foregoing exclusions, neither Party shall be entitled to recover for ***, whether those claimed damages are ***.

9.10 **Entire Agreement; Amendments**. This Agreement, together with the Schedules and Exhibits hereto, contains the entire understanding of the Parties with respect to the subject matter hereof. Any other express or implied agreements and understandings, negotiations, writings and commitments, either oral or written, with respect to the subject matter hereof are superseded by the terms of this Agreement. The Schedules and Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by authorized representative(s) of both Parties hereto (and a duly authorized representative of OPKO with respect to any amendment or modification to Section 6.1 or Section 9.3).

9.11 **Headings**. The captions to the several Articles, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

9.12 **Independent Contractors**. It is expressly agreed that ModeX and Merck shall be independent contractors and that the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither ModeX nor Merck shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party.

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 [***]

9.13 **Waiver**. The waiver by either Party hereto of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise.

9.14 **Waiver of Rule of Construction**. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement shall be construed against the drafting Party shall not apply.

9.15 **Certain Conventions**. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement, unless otherwise indicated. Whenever this Agreement refers to a number of days, unless Business Days are specified, such number refers to calendar days. Unless the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) whenever any provision of this Agreement uses the term "including" (or "includes" or words of similar import), such term will not be limiting and such term will be deemed to mean "including without limitation" (or "includes without limitation"), (e) the word "or" will not be construed as exclusive and shall have the meaning ordinarily ascribed to the phrase "and/or", and (f) references to any Articles or Sections include Sections and subsections that are part of the reference Article or section (e.g., a section numbered "Section 2.2(a)" would be part of "Section 2.2", and references to "Article 2" or "Section 2.2" would refer to material contained in the subsection described as "Section 2.2(a)").

9.16 **Business Day Requirements**. In the event that any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission shall be deemed to be required to be taken on the next occurring Business Day.

9.17 **Counterparts**. This Agreement may be signed in any number of counterparts (including by facsimile or electronic transmission), each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

[*Remainder of page intentionally left blank – Signatures follow*]

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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/ Sunil A. Patel

NAME: Sunil A. Patel

TITLE: SVP, Business Development & Licensing

MODEX THERAPEUTICS, INC.

BY: /s/ Gary J. Nabel

NAME: Gary J. Nabel

TITLE: President and CEO

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

BY: /s/ Steven D. Rubin

NAME: Steven D. Rubin

TITLE: Executive Vice President

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 A

***

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SCHEDULE 1.63

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SCHEDULE 1.77

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SCHEDULE 1.81

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SCHEDULE 4.6

Press Release

OPKO Health's ModeX Therapeutics Enters into Exclusive Worldwide License and Collaboration Agreement with Merck to Develop Epstein-Barr Virus Vaccine Candidate

- *MDX-2201 leverages ModeX's innovative biologics platform to target multiple Epstein-Barr virus (EBV) proteins*

- *EBV is the leading cause of infectious mononucleosis and is also associated with some specific types of cancer*

MIAMI (March 8, 2023) – OPKO Health, Inc. (NASDAQ: OPK) today announced that ModeX Therapeutics, Inc., an OPKO Health company, entered into an exclusive worldwide license and collaboration agreement with Merck, known as MSD outside the United States and Canada, for the development of MDX-2201, ModeX's preclinical nanoparticle vaccine candidate targeting EBV.

"We are delighted to enter this collaboration with Merck to develop a vaccine against EBV, a virus that takes a profound toll on human health worldwide. Targeting four proteins used by EBV to infect cells, this vaccine candidate embodies the novel multitargeting approach developed by ModeX scientists," said Gary Nabel, M.D., Ph.D., President and Chief Executive Officer of ModeX and Chief Innovation Officer of OPKO.

Under the terms of the agreement, OPKO will receive an upfront payment of $50 million and is eligible for milestone payments associated with progress in the development and commercialization of MDX-2201 of up to $872.5 million, as well as royalties on global sales.

ModeX and Merck will jointly advance MDX-2201 to an Investigational New Drug (IND) application filing, after which Merck will be responsible for clinical and regulatory activities, as well as product commercialization. Pre-IND filing activity will be guided by a joint steering committee comprised of representatives from both companies.

"We founded ModeX to develop innovative multispecific biologics for cancer and infectious diseases that target multifactorial pathways that cause illness," said Elias Zerhouni, M.D., President and Vice Chairman of OPKO. "This first collaboration leverages our scientific excellence and innovative platforms along with Merck's discovery and clinical development expertise with the goal of benefiting patients around the world."

"Through the acquisition of ModeX, we broadened our technology foundation and expanded our product pipeline into new therapeutic areas," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO. "Merck represents the ideal partner to develop and commercialize a new vaccine candidate, and we are particularly proud to enter into this high-potential agreement so soon after completing the ModeX transaction last May."

"At Merck we have a proud legacy of developing vaccines including several that have the potential to help protect against certain types of cancer," said Tarit Mukhopadhyay, Ph.D., Vice

President, Infectious Diseases and Vaccine Discovery, Merck Research Laboratories. "We look forward to working with the ModeX Therapeutics team to apply our experience and expertise to evaluate the potential of MDX-2201 to help protect against EBV infection and other, potentially related, conditions."

About MDX-2201

MDX-2201 is based on ModeX's ferritin nanoparticle vaccine platform, which can express as many as 24 copies of a recombinant antigen on its surface to enhance the presentation of key components of the virus and stimulate durable protective immunity. MDX-2201 presents antigens from four viral proteins involved in viral entry into host cells. These include a recombinant antigen designed from the proteins gH, gL and gp42, as well as an antigen derived from gp350. By using ModeX's multi-targeted approach, this combination inhibits infection in two cell types, B cells and epithelial cells, which contrasts from efforts that previously focused on gp350 alone.

This EBV vaccine technology was the subject of preclinical data published in May 2022 in Science Translational Medicine. ModeX scientists previously worked at the Vaccine Research Center, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and Sanofi in the early development of this vaccine candidate. This project also involved collaboration with scientists at the Laboratory of Infectious Diseases, NIAID.

About Epstein-Barr Virus

Epstein-Barr virus (EBV), a member of the herpes virus family, is one of the most common human viruses. Most people are infected with EBV at some point during their lives. EBV can cause infectious mononucleosis, also called mono, and is associated with other illnesses, including some specific types of cancer and multiple sclerosis. There are currently no FDA approved vaccines or treatments for EBV infection.

About ModeX Therapeutics

ModeX Therapeutics is a clinical-stage biopharmaceutical company developing innovative multispecific biologics for cancer and infectious disease. Its platforms unite the power of multiple biologics in a single molecule to create multispecific antibodies and vaccines with unprecedented versatility and potency in fighting complex disease. The ModeX pipeline includes candidates against both solid and hematologic tumors, as well as several of the world's most pressing viral threats. Its founding team includes globally recognized medical innovators with proven track records of delivering breakthroughs for patients. ModeX is an OPKO Health company based in Natick, Massachusetts. For more information, please visit www.modextx.com.

About OPKO Health, Inc.

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies. For more information, visit www.opko.com.

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Cautionary Statement Regarding Forward Looking Statements

This press release contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), which statements may be identified by words such as "expects," "plans," "projects," "will," "may," "anticipates," "believes," "should," "intends," "estimates," and other words of similar meaning, including statements regarding product development efforts, expected benefits of MDX-2201 and ModeX's ferritin nanoparticle vaccine platform, whether the collaboration with Merck will be successful, whether clinical trials for MDX-2201 will support marketing approval, whether MDX-2201 will be successfully developed or commercialized or meet expectations regarding its efficacy, safety and market potential, whether OPKO will receive milestone or royalty payments for development and commercialization of MDX-2201, expectations about the global EBV market, whether MDX-2201 has the potential to be first in class and will be approved by the FDA, as well as other non-historical statements, including statements about our expectations, products, beliefs or intentions regarding ModeX, projected future clinical developments, the potential for ModeX products and pipeline and any other statements regarding OPKO's and ModeX's future expectations, beliefs, plans, product candidates, objectives, financial conditions, assumptions or future events or performance. 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 in our Annual Reports on Form 10-K filed and to be filed with the Securities and Exchange Commission and under the heading "Risk Factors" in our other filings with the Securities and Exchange Commission. In addition, forward-looking statements may also be adversely affected by general market factors, competitive product development, product availability, federal and state regulations and legislation, the regulatory process for new products and indications, manufacturing issues that may arise, patent positions and litigation, among other factors. The forward-looking statements contained in this press release speak only as of the date the statements were made, and we do not undertake any obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA.

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SCHEDULE 5.3.5(b)

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SCHEDULE 6.2

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SCHEDULE 6.2.7

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SCHEDULE 6.3.2

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