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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 September 30, 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 (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes □ No

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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	x	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 November 1, 2023, the registrant had 773,056,533 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 successfully commercialize Somatrogon (hGH-CTP);
- that we may not generate or sustain profits or cash flow from our laboratory operations or substantial revenue from Somatrogon (hGH-CTP), *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 businesses;
- 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.;
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations.
- disruptions to operations, including impact on employees, and business continuity, including physical damage or impaired access to company facilities, office of technology from the current conflict in Israel and the Gaza Strip

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

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 138,621	$ 153,191
Accounts receivable, net	117,449	127,312
Inventory, net	68,960	74,060
Other current assets and prepaid expenses	32,209	39,962
Total current assets	357,239	394,525
Property, plant and equipment, net	78,170	82,879
Intangible assets, net	758,414	823,520
In-process research and development	195,000	195,000
Goodwill	594,457	595,851
Investments	19,377	28,080
Operating lease right-of-use assets	44,690	38,725
Other assets	9,333	8,679
Total assets	$ 2,056,680	$ 2,167,259
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 66,801	$ 66,993
Accrued expenses	92,368	98,269
Current maturities of operating leases	11,267	11,628
Current portion of convertible notes	—	3,050
Current portion of lines of credit and notes payable	30,118	33,540
Total current liabilities	200,554	213,480
Operating lease liabilities	34,649	27,963
Long term portion of convertible notes	213,285	210,371
Deferred tax liabilities	138,007	126,426
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	25,617	27,371
Total long-term liabilities	411,558	392,131
Total liabilities	612,112	605,611
Equity:		
Common Stock - $0.01 par value, 1,000,000,000 shares authorized; 781,711,885 and 781,306,164 shares issued at September 30, 2023 and December 31, 2022, respectively	7,817	7,813
Treasury Stock - 8,655,082 shares at September 30, 2023 and December 31, 2022, respectively	(1,791)	(1,791)
Additional paid-in capital	3,430,340	3,421,872
Accumulated other comprehensive loss	(46,495)	(43,323)
Accumulated deficit	(1,945,303)	(1,822,923)
Total shareholders' equity	1,444,568	1,561,648
Total liabilities and equity	$ 2,056,680	$ 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 September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Revenues:				
Revenue from services	$ 131,679	$ 142,856	$ 391,100	$ 616,259
Revenue from products	40,670	32,388	124,553	104,938
Revenue from transfer of intellectual property and other	6,246	4,500	165,938	97,659
Total revenues	178,595	179,744	681,591	818,856
Costs and expenses:				
Cost of service revenue	106,375	128,182	333,460	521,221
Cost of product revenue	24,543	20,263	74,711	65,410
Selling, general and administrative	72,240	79,674	227,676	298,675
Research and development	19,435	18,792	70,199	54,359
Contingent consideration	(1,125)	(754)	(1,023)	(685)
Amortization of intangible assets	21,534	21,407	64,543	66,225
Gain on sale of assets	—	—	—	(15,365)
Total costs and expenses	243,002	267,564	769,566	989,840
Operating loss	(64,407)	(87,820)	(87,975)	(170,984)
Other income and (expense), net:				
Interest income	970	667	3,077	838
Interest expense	(3,384)	(3,017)	(10,053)	(8,754)
Fair value changes of derivative instruments, net	88	446	(829)	652
Other expense, net	(11,645)	(36,651)	(16,045)	(111,091)
Other expense, net	(13,971)	(38,555)	(23,850)	(118,355)
Loss before income taxes and investment losses	(78,378)	(126,375)	(111,825)	(289,339)
Income tax benefit (provision)	(6,075)	40,327	(10,456)	46,524
Net loss before investment losses	(84,453)	(86,048)	(122,281)	(242,815)
Loss from investments in investees	(20)	(43)	(99)	(359)
Net loss	$ (84,473)	$ (86,091)	$ (122,380)	$ (243,174)
Loss per share, basic and diluted:				
Loss per share	$ (0.11)	$ (0.11)	$ (0.16)	$ (0.34)
Weighted average common shares outstanding, basic and diluted	751,525,007	750,396,263	751,716,692	708,121,980

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 September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Net loss	$ (84,473)	$ (86,091)	$ (122,380)	$ (243,174)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive loss	(9,554)	(8,855)	(3,173)	(27,531)
Comprehensive loss	$ (94,027)	$ (94,946)	$ (125,553)	$ (270,705)

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 and nine months ended September 30, 2023

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at June 30, 2023	781,693,135	$ 7,817	(8,655,082)	$ (1,791)	$ 3,427,094	$ (36,942)	$ (1,860,830)	$ 1,535,348
Equity-based compensation expense	—	—	—	—	3,218	—	—	3,218
Exercise of common stock options and warrants	18,750	0	—	—	28	—	—	28
Net loss	—	—	—	—	—	—	(84,473)	(84,473)
Other comprehensive loss	—	—	—	—	—	(9,553)	—	(9,553)
Balance at September 30, 2023	781,711,885	$ 7,817	(8,655,082)	$ (1,791)	$ 3,430,340	$ (46,495)	$ (1,945,303)	$ 1,444,568

	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	—	—	—	—	8,745	—	—	8,745
Exercise of common stock options and warrants	405,721	4	—	—	(277)	—	—	(273)
Net loss	—	—	—	—	—	—	(122,380)	(122,380)
Other comprehensive loss	—	—	—	—	—	(3,172)	—	(3,172)
Balance at September 30, 2023	781,711,885	$ 7,817	(8,655,082)	$ (1,791)	$ 3,430,340	$ (46,495)	$ (1,945,303)	$ 1,444,568

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 and nine months ended September 30, 2022

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at June 30, 2022	780,591,681	$ 7,806	(8,655,082)	$ (1,791)	$ 3,413,556	$ (49,171)	$ (1,651,601)	$ 1,718,799
Equity-based compensation expense	—	—	—	—	3,390	—	—	3,390
Exercise of common stock options and warrants	27,750	1	—	—	(464)	—	—	(463)
ModeX Acquisition	721,800	7	—	—	2,281	—	—	2,288
Net loss	—	—	—	—	—	—	(86,091)	(86,091)
Other comprehensive loss	—	—	—	—	—	(8,855)	—	(8,855)
Balance at September 30, 2022	781,341,231	$ 7,814	(8,655,082)	$ (1,791)	$ 3,418,763	$ (58,026)	$ (1,737,692)	$ 1,629,068

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive 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	—	—	—	—	15,315	—	—	15,315
Exercise of common stock options and warrants	629,837	7	—	—	(695)	—	—	(688)
Adoption of ASU 2020-06	—	—	—	—	(39,100)	—	17,458	(21,642)
ModeX Acquisition	90,629,111	906	—	—	220,756	—	—	221,662
Net loss	—	—	—	—	—	—	(243,174)	(243,174)
Other comprehensive loss	—	—	—	—	—	(27,531)	—	(27,531)
Balance at September 30, 2022	781,341,231	$ 7,814	(8,655,082)	$ (1,791)	$ 3,418,763	$ (58,026)	$ (1,737,692)	$ 1,629,068

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 nine months ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (122,380)	$ (243,174)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	79,315	82,195
Non-cash interest	2,057	2,057
Amortization of deferred financing costs	908	863
Losses from investments in investees	99	359
Equity-based compensation – employees and non-employees	8,746	15,315
Realized loss on disposal of fixed assets and sales of equity securities	1,444	(814)
Change in fair value of equity securities and derivative instruments	14,406	104,126
Change in fair value of contingent consideration	(1,023)	(685)
Gain on sale of GeneDx	—	(15,365)
Deferred income tax benefit	7,307	(48,883)
Changes in assets and liabilities:		
Accounts receivable, net	8,741	130,052
Inventory, net	4,082	11,314
Other current assets and prepaid expenses	10,220	(3,977)
Other assets	(2,666)	211
Accounts payable	191	(25,000)
Foreign currency measurement	24	10,541
Contract liabilities	(2)	(73)
Accrued expenses and other liabilities	(1,372)	(82,631)
Net cash provided by (used in) operating activities	10,097	(63,569)
Cash flows from investing activities:		
Investments in investees	(5,000)	—
Proceeds from sale of equity securities	364	—
Proceeds from sale of GeneDx	—	115,423
Acquisition of businesses, net of cash	—	228
Proceeds from the sale of property, plant and equipment	1,109	1,501
Capital expenditures	(13,253)	(18,242)
Net cash provided by (used in) investing activities	(16,780)	98,910
Cash flows from financing activities:		
Proceeds from the exercise of common stock options	(273)	(688)
Borrowings on lines of credit	515,318	893,548
Repayments of lines of credit	(519,597)	(880,033)
Redemption of 2033 Senior Notes	(3,000)	—
Net cash provided by (used in) financing activities	(7,552)	12,827
Effect of exchange rate changes on cash and cash equivalents	(335)	(2,040)
Net increase (decrease) in cash and cash equivalents	(14,570)	46,128
Cash and cash equivalents at beginning of period	153,191	134,710
Cash and cash equivalents at end of period	$ 138,621	$ 180,838
SUPPLEMENTAL INFORMATION:		
Interest paid	$ 10,748	$ 7,019
Income taxes paid, net of refunds	$ (823)	$ 4,471
Assets acquired by finance leases	$ 713	$ —
Operating lease right-of-use assets obtained in exchange for lease obligations	$ 5,966	$ —
Non-cash financing:		
Shares issued upon the conversion of:		
Common stock options, warrants, and restricted stock units surrendered in net exercise	$ 301	$ 1,182
Issuance of common stock for acquisition of ModeX	$ —	$ 221,662
Fair value of shares received included in consideration from GeneDx Holdings	$ 6,689	$ 172,000

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 have partnered with Pfizer Inc. ("Pfizer") with respect to Somatrogon (hGH-CTP)'s further development. Regulatory applications for Somatrogon (hGH-CTP) have been approved in more than 40 markets worldwide, including the United States, European Union Member States, Japan, Canada, and Australia 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. In May 2022, we acquired ModeX Therapeutics, Inc. ("ModeX"), a biotechnology company focused on developing innovative multi-specific immune therapies for cancer and infectious disease 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 Natick, Massachusetts, Waterford, Ireland, Kiryat Gat, Israel, and Barcelona, Spain.

On May 9, 2022, the Company entered into an Agreement and Plan of Merger (the "ModeX Merger Agreement"), pursuant to which the Company acquired ModeX. The Company paid the entirety of the $300.0 million purchase price pursuant to the issuance of an aggregate of 89,907,310 shares of the Company's common stock, par value $0.01 per share ("Common Stock"), to the former stockholders of ModeX. Please see Note 6 for additional information.

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 "Sema4 Holdings Corp."), a Delaware corporation ("GeneDx Holdings"), pursuant to which, on April 28, 2022, GeneDx Holdings acquired the Company's former subsidiary, GeneDx LLC, (f/k/a GeneDx, Inc. "GeneDx").

At 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 with GeneDx Holdings, pursuant to which the Company agreed to certain lockup restrictions in respect the shares of GeneDx Holdings Common Stock held by the Company. Additionally, 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. 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, and the Company has also agreed to vote its shares of GeneDx Holdings Common Stock in accordance with the recommendations of GeneDx Holdings' board of directors for so long as it continues to hold at least 5% of the outstanding shares of GeneDx Holdings Common Stock. Please see Note 6 for additional information.

NOTE 2 FOREIGN EXCHANGE RATES

Foreign Currency Exchange Rates

Approximately 30.7% of revenue for the nine months ended September 30, 2023, and approximately 22.0% of revenue for the nine months ended September 30, 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 affect the translation of revenues and expenses denominated in foreign currencies into USD for purposes of reporting the consolidated financial results. During the nine months ended September 30, 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 $43.1 million and $39.9 million at September 30, 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 seek to 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 September 30, 2023, we had 13 open foreign exchange forward contracts relating to inventory purchases on letters of credit with various amounts maturing monthly through October 2023 with a notional value totaling approximately $0.7 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 nine months ended September 30, 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 and nine months ended September 30, 2023, was $2.6 million and $4.0 million, respectively. Inventory obsolescence expense for the three and nine months ended September 30, 2022, was $3.0 million and $4.0 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 September 30, 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 $594.5 million and $595.9 million, respectively, at September 30, 2023 and December 31, 2022.

Net intangible assets other than goodwill was $1.0 billion on September 30, 2023, and December 31, 2022, respectively, including IPR&D of $195.0 million on September 30, 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.

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.

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 $64.5 million for the three and nine months ended September 30, 2023, respectively. Amortization expense was $21.4 million and $66.2 million for the three and nine months ended September 30, 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 September 30, 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 applicable acquisitions to their respective fair values and record increases in fair value as contingent consideration expense and decreases in 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 September 30, 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 $4.8 million and $14.8 million for the three and nine months ended September 30, 2023, respectively. Depreciation expense was $5.0 million and $16.0 million for the three and nine months ended September 30, 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 nine months ended September 30, 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 merit. We intend to exhaust all judicial remedies necessary to resolve the matter, 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 September 30, 2023 and December 31, 2022, receivable balances (net of explicit and implicit price concessions) from Medicare and Medicaid were 11.6% and 14.2%, 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 September 30, 2023 and December 31, 2022, receivables due from patients represented approximately 2.1% 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 $2.0 million and $4.2 million on September 30, 2023, and December 31, 2022, respectively. The credit loss expense for the three and nine months ended September 30, 2023, was $98.3 thousand and $183.4 thousand, respectively. The credit loss expense for the three and nine months ended September 30, 2022, was $57.9 thousand and $241.5 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 and nine months ended September 30, 2023, we recorded $3.2 million and $8.7 million, respectively, of equity-based compensation expense. For the three and nine months ended September 30, 2022, we recorded $3.4 million and $15.3 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 is Phillip Frost, M.D., our Chairman and Chief Executive Officer. Dr. Frost 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 laboratory operations through BioReference. 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 use 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 and nine months ended September 30, 2023, we recorded ($3.8 million) and $1.9 million), respectively, of transaction losses. During the three and nine months ended September 30, 2022, we recorded ($5.8 million) and ($7.6 million), respectively, of transaction losses.

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 December 2022, the European Union member states voted unanimously to adopt a Directive implementing the Pillar 2 (global minimum tax) rules, giving member states until December 31, 2023, to implement the Directive into national legislation. Further details regarding implementing these rules are expected, and if implemented, such reform may increase our tax liabilities and compliance costs and reduce our profitability. Pillar 2 is effective from January 1, 2024, and will be treated as a period cost in future years and will not impact operating results for 2023.

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 83,074,689 and 55,304,353 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the three months ended September 30, 2023 and 2022, respectively, because their inclusion would be antidilutive. A total of 82,368,398 and 56,529,876 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the nine months ended September 30, 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 September 30, 2023, 18,750 options were exercised and no restricted stock units vested, resulting in the issuance of 18,750 shares of Common Stock.

During the nine months ended September 30, 2023, 18,750 options were exercised and 549,680 restricted stock units vested, resulting in the issuance of 405,721 shares of Common Stock.

During the three months ended September 30, 2022, an aggregate of 27,750 options to purchase shares of our Common Stock were exercised and 937,836 restricted stock units vested, resulting in the issuance of 749,550 shares of Common Stock. Of the 965,586 aggregate number of options exercised and restricted stock units vested, 216,036 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of such instruments.

During the nine months ended September 30, 2022, an aggregate of 211,187 options to purchase shares of our Common Stock were exercised and 1,599,212 restricted stock units vested, resulting in the issuance of 1,351,637 shares of Common Stock. Of the 1,810,399 aggregate number of options exercised and restricted stock units vested, 458,762 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise or settlement feature of such instruments.

NOTE 5 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	September 30, 2023	December 31, 2022
Accounts receivable, net:		
Accounts receivable	$ 119,397	$ 131,474
Less: allowance for credit losses	(1,948)	(4,162)
	$ 117,449	$ 127,312
Inventories, net:		
Consumable supplies	$ 27,259	$ 31,275
Finished products	35,053	37,139
Work in-process	2,589	2,449
Raw materials	8,691	6,771
Less: inventory reserve	(4,632)	(3,574)
	$ 68,960	$ 74,060
Other current assets and prepaid expenses:		
Taxes recoverable	$ 7,452	$ 8,191
Prepaid expenses	9,483	7,918
Prepaid insurance	6,667	4,496
Other receivables	1,604	13,105
Other	7,003	6,252
	$ 32,209	$ 39,962
Intangible assets, net:		
Customer relationships	$ 314,337	$ 314,854
Technologies	824,263	826,282
Trade names	49,743	49,752
Covenants not to compete	12,909	12,911
Licenses	6,186	5,988
Product registrations	6,613	6,831
Other	5,807	5,861
Less: accumulated amortization	(461,444)	(398,959)
	$ 758,414	$ 823,520
Accrued expenses:		
Employee benefits	$ 38,242	$ 33,765
Clinical trials	6,328	4,700
Commitments and contingencies	5,533	4,295
Inventory received but not invoiced	1,653	7,830
Finance leases short-term	2,931	2,809
Professional fees	1,911	1,820
Taxes payable	3,720	5,351
Royalties	1,509	2,323
Commissions	1,922	1,471
Contingent consideration	—	62
Other	28,619	33,843
	$ 92,368	$ 98,269
Other long-term liabilities:		
Mortgages and other debts payable	$ 7,892	$ 9,098
Finance leases long-term	7,680	7,089
Contract liabilities	136	138
Contingent consideration	—	974
Other	9,909	10,072
	$ 25,617	$ 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 nine months ended September 30, 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 nine months ended September 30, 2023.

	2023				
(In thousands)	Gross goodwill at January 1	Cumulative impairment at January 1	Acquisitions, dispositions and other	Foreign exchange and other	Balance at September 30
Pharmaceuticals					
CURNA	$ 4,827	$ (4,827)	$ —	$ —	$ —
Rayaldee	81,786	—	—	(962)	80,824
FineTech	11,698	(11,698)	—	—	—
ModeX	80,432	—	(172)	—	80,260
OPKO Biologics	139,784	—	—	—	139,784
OPKO Chile	3,767	—	—	(174)	3,593
OPKO Health Europe	7,057	—	—	(86)	6,971
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)	$ (172)	$ (1,222)	$ 594,457

NOTE 6 ACQUISITIONS AND INVESTMENTS

ModeX Acquisition

On May 9, 2022, the Company entered into the ModeX Merger Agreement, pursuant to which the Company acquired ModeX. The Company paid the entirety of the $300.0 million purchase price pursuant to the issuance of shares of Common Stock to the former stockholders of ModeX. Such 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 of the acquisition. Included in the total purchase price of $221.7 million were $2.3 million of fully vested equity awards.

The following table summarizes the final purchase price allocation and the fair value of the net assets acquired and liabilities assumed at the date of acquisition of ModeX at the date of acquisition:

(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 $3.7 million. Net loss in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2023, includes $14.3 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 September 30, 2023 and December 31, 2022:

(in thousands)	As of September 30, 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	$ (0)	$ 2,348	$ 103	$ 4,120
Variable interest entity, equity method	804	675	800	1,370
Equity method investments - FV option	12,953		21,120	
Equity securities	237		648	
Equity securities with no readily determinable fair value	5,381		5,381	
Warrants and options	1		28	
Total carrying value of investments	$ 19,377		$ 28,080	

Equity method investments

Our equity method investments, other than GeneDx Holdings, as described below, consist of investments in Pharmsynthez (ownership 9%), Cocrystal Pharma, Inc. ("COCP") (2%), Non-Invasive Monitoring Systems, Inc. ("NIMS") (1%), BioCardia, Inc. ("BioCardia") (1%), Xenetic Biosciences, Inc. ("Xenetic") (3%), and LeaderMed Health Group Limited ("LeaderMed") (47%). Neovasc, Inc. in which we owned 0.5%, was acquired by Shockwave Medical, Inc. in April 2023, and during the third quarter of 2023, we received $363 thousand in merger consideration in exchange for our shares. The aggregate amount of assets, liabilities, and net losses of these equity method investees as of and for the nine months ended September 30, 2023 were $92.0 million, $27.5 million, and $29.1 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 September 30, 2023 and December 31, 2022 was $1.1 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. Additionally, subject to GeneDx having achieved certain revenue targets for the year ended December 31, 2022, and achieving certain revenue targets for the year ending December 31, 2023, we are eligible to receive the 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 April 2023, GeneDx Holdings announced a 1-for-33 reverse stock split of the GeneDx Holdings Common Stock. The 1-for-33 reverse stock split automatically converted 33 current shares of GeneDx Common Stock into one new share of GeneDx Common Stock. As of September 30, 2023, we held 3,558,602 shares of GeneDx Holdings Common Stock, representing an approximate 13.8% ownership interest in GeneDx Holdings.

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 seven 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 and nine months ended September 30, 2023, we recognized $8.3 million and $19.9 million of expense related to the change in fair value of our GeneDx Holdings investment. As of September 30, 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 $13.0 million.

Investments in Equity Securities

Our equity securities consist of investments in VBI Vaccines Inc. (1%), ChromaDex Corporation ("ChromaDex") (0.10%), Eloxx Pharmaceuticals, Inc. ("Eloxx") (1%), 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 nine months ended September 30, 2023 and 2022 were as follows:

	For the nine months ended September 30,	
(in thousands)	2023	2022
Equity Securities:		
Net gains and losses recognized during the period on equity securities	$ (411)	$ (2,999)
Unrealized net losses recognized during the period on equity securities still held at the reporting date	$ (411)	$ (2,999)

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 September 30, 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 September 30, 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, was a founder of Zebra. 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 September 30, 2023 and December 31, 2022, our debt consisted of the following:

(In thousands)	September 30, 2023	December 31, 2022
2025 Notes	$ 142,953	$ 142,096
2023 Convertible Notes	70,332	68,275
2033 Senior Notes	—	3,050
JP Morgan Chase	15,027	18,080
Chilean and Spanish lines of credit	13,320	13,740
Current portion of notes payable	1,772	1,720
Long term portion of notes payable	7,927	9,290
Total	$ 251,331	$ 256,251
Balance sheet captions		
Current portion of convertible notes	$ —	$ 3,050
Long term portion of convertible notes	213,285	210,371
Current portion of lines of credit and notes payable	30,119	33,540
Long Term notes payable included in long-term liabilities	7,927	9,290
Total	$ 251,331	$ 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 redeem for cash any or all of the 2025 Notes, at our option, 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 both September 30, 2023 and December 31, 2022, a total of 21,144,825 shares remained outstanding under the share lending arrangement. 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 September 30, 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	—	857	857
Balance at September 30, 2023	$ 144,580	$ (1,627)	$ 142,953

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 and each holder of a 2023 Convertible Note originally had 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. On February 10, 2023, we amended the 2023 Convertible Notes to extend the maturity to January 31, 2025 and 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 per share. Interest under the 2023 Convertible Notes accrues 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.

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.

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. 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, and, 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.

During the first quarter of 2023, we paid approximately $3.0 million to purchase the remaining 2033 Senior Notes in accordance with the indenture governing the 2033 Senior Notes, following which no 2033 Senior Notes remained outstanding.

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.

On June 29, 2023, the company entered into a Waiver and Amendment No. 2 to the Credit Agreement (the "Credit Agreement Amendment"). The Credit Agreement Amendment, among other things, (i) waived specific defaults under the Credit Agreement resulting from the failure to pledge certain intellectual property, (ii) replaced the London interbank offered rate (LIBOR) with the forward-looking term rate based on the secured overnight financing rate (the "SOFR Rate") as the interest rate benchmark, (iii) reduced the aggregate revolving commitment from $75,000,000 to $50,000,000, (iv) provided a revised commitment fee rate, and (v) extended the maturity date from August 2024 to the earlier of August 2025, and 90 days prior to the maturity date of any indebtedness of the Company in an aggregate principal amount exceeding $7,500,000.

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 September 30, 2023, $11.3 million remained available for borrowing under the Credit Agreement. Principal under the Credit Agreement is due upon maturity on August 30, 2025.

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 (x) the prime rate and (y) the SOFR Rate for an interest period of one month plus 2.50% and a benchmark spread adjustment of 0.10%) plus an applicable margin of 1.00%; or (ii) the SOFR Rate plus a benchmark spread adjustment of 0.10% and an applicable margin of 2.00%. 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 0.400% if the average quarterly availability is 50% or more of the revolving commitment, or 0.275% if the average quarterly availability is less than or equal to 50% of the revolving commitments.

As of September 30, 2023 and December 31, 2022, $15.0 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 September 30, 2023, BioReference and its subsidiaries had net assets of approximately $529.1 million, which included goodwill of $283.0 million and intangible assets of $172.8 million.

In addition to the Credit Agreement, we had line of credit agreements with thirteen other financial institutions as of September 30, 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 September 30, 2023	Credit line capacity	September 30, 2023	December 31, 2022
JPMorgan Chase	9.50%	$ 50,000	$ 15,027	$ 18,080
Itau Bank	5.50%	1,900	1,237	2,378
Bank of Chile	6.60%	2,500	1,688	817
BICE Bank	5.50%	2,799	2,799	1,661
Scotiabank	5.00%	5,500	1,176	1,646
Santander Bank	5.50%	5,000	1,009	1,238
Security Bank	5.50%	1,400	303	755
Estado Bank	5.50%	4,000	2,798	1,621
BCI Bank	5.00%	2,500	998	2,100
Internacional Bank	5.50%	1,500	897	599
Consorcio Bank	5.00%	2,000	414	925
Banco De Sabadell	1.75%	529	—	—
Santander Bank	1.95%	529	—	—
Total		$ 80,157	$ 28,348	$ 31,820

At September 30, 2023 and December 31, 2022, the weighted average interest rate on our lines of credit was approximately 7.6% and 5.4%, respectively.

At September 30, 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)	September 30, 2023	December 31, 2022
Current portion of notes payable	$ 1,772	$ 1,720
Other long-term liabilities	7,927	9,290
Total	$ 9,699	$ 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 3.0% on September 30, 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 nine months ended September 30, 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 loss	(3,173)
Balance at September 30, 2023	$ (46,496)

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 September 30, 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 September 30, 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	$ 58,798	$ —	$ —	$ 58,798
Equity securities	237	—	—	237
Equity Method - FV option	12,953	—	—	12,953
Common stock options/warrants	—	1	—	1
Forward contracts	—	58	—	58
Total assets	$ 71,988	$ 59	$ —	$ 72,047

(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)	September 30, 2023				
	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2025 Notes	$ 142,953	$ 142,330	$ —	$ 142,330	$ —

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 September 30, 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 September 30, 2023:

(In thousands)	September 30, 2023
	Contingent consideration
Balance at December 31, 2022	$ 1,036
Change in fair value:	
Included in results of operations	(1,023)
Foreign currency impact	(13)
Balance at September 30, 2023	$ —

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 the CURNA and OPKO Renal transactions. As of September 30, 2023, we had no contingent consideration recorded in accrued expenses and 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	September 30, 2023	December 31, 2022
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 1	$ 28
Forward contracts	Unrealized losses on forward contracts are recorded in Accrued expenses.	$ 58	$ (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 September 30, 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 nine months ended September 30, 2023 and 2022:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	2023	2022	2023	2022
Derivative loss:				
Common Stock options/warrants	$ (37)	$ 10	$ (27)	$ 5
Forward contracts	125	436	(802)	647
Total	$ 88	$ 446	$ (829)	$ 652

NOTE 11 RELATED PARTY TRANSACTIONS

On October 12, 2023, the Company entered into an E-Commerce Distribution Agreement with NextPlat Corp ("NextPlat"), a global e-commerce provider, in which Dr. Frost owns more than 20% interest. Under the terms of the agreement, NextPlat will launch an OPKO Health-branded online storefront on Alibaba Group Holding Limited Tmall Global e-commerce platform in China featuring an assortment of nutraceutical and veterinary products sold and distributed by OPKO Health Europe SLU, our wholly-owned subsidiary.

On May 4, 2023, the Company entered into an Assignment and Assumption Agreement (the "Assignment Agreement") with Ruen-Hui Biopharmaceuticals, Inc., a Taiwanese entity ("Ruen-Hui") in which Dr. Hsiao owns more than a 10% interest. Ruen-Hui assumed the Company's obligations under an exclusive license agreement with Academia Sinica in exchange for an upfront payment of $150,000, a number of potential milestone payments up to $1 million, commercial milestones ranging from low to double digit millions, and royalty payments. The Assignment Agreement will be effective upon Academia Sinica's consent to the assignment. Ruen Hui will also be responsible for any outstanding payment obligations under such license agreement, including patent maintenance costs, and any payments due to Academia Sinica.

On April 29, 2022, upon consummation of our sale of GeneDx, 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 August 31, 2023, including human resources, information technology support, and finance and accounting. As of September 30, 2023, the Company had incurred aggregate expenses of $2.6 million for services rendered under the Transition Services Agreement. For the nine months ended September 30, 2023, the company incurred expenses of $1.3 million for services rendered under the Transaction Services Agreement. As of September 30, 2023, the company has a receivable of $0.2 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%), ChromaDex (0.10%), COCP (2%), NIMS (1%), Eloxx (1%), BioCardia (1%) and LeaderMed Health Group Limited (47%). Neovasc, Inc., in which we owned 0.5%, was acquired by Shockwave Medical, Inc. in April 2023, and during the third quarter of 2023, we received $363 thousand in merger consideration in exchange for our shares. 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 13.8% ownership interest as a result of our sale of GeneDx, Inc. and subsequent participation in an underwritten offering by GeneDx Holdings. Richard 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 $2.4 million, $2.0 million, and $0.3 million, respectively, during the nine months ended September 30, 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 and nine months ended September 30, 2023, we reimbursed and accrued approximately $49.5 thousand and $78.8 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2022, we reimbursed and accrued approximately $0.0 thousand and $30.0 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 of September 30, 2023, we had no contingent consideration recorded in accrued expenses and other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. As of December 31, 2022, $1.0 million of contingent consideration was recorded in accrued expenses and other long-term liabilities. Refer to Note 5.

GeneDx, 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 and the Texas Medicaid Office of the Inspector General have reached an agreement in principle to settle this matter for approximately $231 thousand.

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 September 30, 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 $44.0 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 $19.8 million and $27.8 million, respectively, for the nine months ended September 30, 2023 and 2022. Revenue adjustments for the nine months ended September 30, 2023 were 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 September 30, 2023 and December 31, 2022, we had liabilities of approximately $2.9 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 and nine months ended September 30, 2023 and 2022 was as follows:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	2023	2022	2023	2022
Healthcare insurers	$ 81,469	$ 58,076	$ 238,934	$ 242,915
Government payers	19,909	20,151	61,250	74,938
Client payers	25,906	61,699	77,973	286,423
Patients	4,395	2,930	12,943	11,983
Total	$ 131,679	$ 142,856	$ 391,100	$ 616,259

Revenue from products

We recognize revenue from product sales when a customer obtains control of promised goods or services. The amount of revenue 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 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 and nine months ended September 30, 2023, we recognized $7.3 million and $21.7 million, respectively, in net product revenue from sales of *Rayaldee*. For the three and nine months ended September 30, 2022, we recognized $6.9 million and $18.2 million, respectively, in net product revenue from sales of *Rayaldee*.

The following table presents an analysis of *Rayaldee* product sales allowances and accruals for the three and nine months ended September 30, 2023 and 2022:

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at June 30, 2023	$ 2,330	$ 5,954	$ 1,634	$ 9,918
Provision related to current period sales	3,446	4,998	322	8,766
Credits or payments made	(4,125)	(4,207)	(15)	(8,347)
Balance at September 30, 2023	$ 1,651	$ 6,745	$ 1,941	$ 10,337
Total gross Rayaldee sales				$ 16,090
Provision for Rayaldee sales allowances and accruals as a percentage of gross Rayaldee sales				54%

(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	10,702	14,604	959	26,265
Credits or payments made	(10,583)	(12,922)	(701)	(24,206)
Balance at September 30, 2023	$ 1,651	$ 6,745	$ 1,941	$ 10,337
Total gross Rayaldee sales				$ 47,940
Provision for Rayaldee sales allowances and accruals as a percentage of gross Rayaldee sales				55%

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at June 30, 2022	$ 1,669	$ 6,489	$ 1,618	$ 9,776
Provision related to current period sales	3,191	4,158	269	7,618
Credits or payments made	(2,892)	(3,261)	(400)	(6,553)
Balance at September 30, 2022	$ 1,968	$ 7,386	$ 1,487	$ 10,841
Total gross Rayaldee sales				$ 14,497
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	9,816	14,469	846	25,131
Credits or payments made	(9,862)	(12,582)	(1,998)	(24,442)
Balance at September 30, 2022	$ 1,968	$ 7,386	$ 1,487	$ 10,841
Total gross Rayaldee sales				$ 43,358
Provision for Rayaldee sales allowances and accruals as a percentage of gross Rayaldee sales				58%

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 and nine months ended September 30, 2023, we recorded $6.2 million and $165.9 million of revenue from the transfer of intellectual property and other, respectively. For the three months ended September 30, 2023 and 2022, revenue from transfer of intellectual property and other included revenue of $4.9 million and $1.4 million, respectively, of royalty revenue from sales of NGENLA (Somatrogon) in Europe and Japan. For the three months ended September 30, 2023 and 2022, revenue from transfer of intellectual property and other included $0.9 million and $2.2 million, respectively, related to the Pfizer Transaction (as defined below). For the nine months ended September 30, 2023, revenue from transfer of intellectual property and other principally reflects $90.0 million triggered by the FDA approval of NGENLA (Somatrogon) and during the nine months ended September 30, 2022, includes $85.0 million of regulatory milestone payments from Pfizer due from the commencement of sales of NGENLA (Somatrogon) in Europe and Japan. For the nine months ended September 30, 2023 and 2022, revenue from transfer of intellectual property and other includes revenue of $11.8 million and $1.4 million, respectively, of royalty revenue from sales of NGENLA (Somatrogon) in Europe and Japan. For the nine months ended September 30, 2023, revenue from transfer of intellectual property and other reflects a $50.0 million payment from Merck in consideration for the rights granted to Merck under the Merck Agreement (as defined below), a $7.0 million payment from Vifor (as defined below) triggered by the German price approval for *Rayaldee* and 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. For the nine months ended September 30, 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 nine months ended September 30, 2023 were as follows:

(In thousands)		
Balance at December 31, 2022	$	138
Balance at September 30, 2023		136
Revenue recognized in the period from:		
Amounts included in contracts liability at the beginning of the period		2

NOTE 14 STRATEGIC ALLIANCES

Biomedical Advanced Research and Development Authority

On September 28, 2023, ModeX was awarded a contract (the "BARDA Contract") from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Administration for Strategic Preparedness and Response at the U.S. Department of Health and Human Services, to advance a platform and specific candidates designed to address a range of public health threats in viral infectious diseases. The awarded funding will enable research, development and clinical evaluation of potent multispecific antibodies, based on ModeX proprietary MSTAR technology. MSTAR is a flexible plug-and-play platform able to incorporate four to six independent antibody binding sites into a single molecule, dramatically expanding its therapeutic potential while enabling rapid responses to emerging infections and their viral variants, including COVID-19, influenza, and other pathogens.

The BARDA Contract is cost plus fixed fee, pursuant to which we will receive an initial $59.0 million payment over a five-year period from September 2023 to February 2028 for the development, manufacturing, and execution of a Phase 1 clinical trial for a next-generation MSTAR multispecific antibody with broad neutralizing activity against known variants of SARS-CoV-2. We are eligible to receive up to an additional $109.6 million from BARDA upon achieving particular milestones to develop multispecific antibodies targeting other viral pathogens such as influenza. BARDA will make periodic assessments of progress, and the continuation of the BARDA Contract is based on ModeX's performance thereunder, the timeliness and quality of deliverables, and certain other factors. The BARDA Contract contains a number of terms and conditions that are customary for government contracts of this nature, including provisions giving BARDA the right to terminate the BARDA Contract at any time in its sole discretion.

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 develop, manufacture, use and commercialize (i) a multivalent or monovalent vaccine assembled using 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 paid $12.5 million to Sanofi during the second quarter of 2023.

As part of their strategic collaboration, ModeX and Merck have put in place a research plan to manage research and other development activities related to the development of a Vaccine or Product including a joint steering committee to facilitate the research program. As part of the research plan, they will use a third-party contract development and manufacturing organization ("CDMO") to carry out such activities unless otherwise agreed. Development costs incurred by ModeX in furtherance of these development activities will be reimbursed by Merck. To date, we have spent $10.8 million of development costs related to the Epstein -Barr Virus, for which Merck will provide reimbursement.

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 is 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 equated 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. CAMP4 has informed the Company that the FDA has placed the Dravet clinical trials on hold as CAMP4 is pursuing strategies to potentially advance to clinical trials.

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 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 nine months ended September 30, 2023. For the nine months ended September 30, 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 June 2023, The FDA approved NGENLA (Somatrogon (hGH-CTP)) a once-weekly injection to treat pediatric growth hormone deficiency in the United States. In early 2022, the European Commission and Ministry of Health, Labour and Welfare in Japan approved NGENLA (Somatrogon) in those territories. We have also received pricing approvals in Germany and Japan. NGENLA (Somatrogon (hGH-CTP)) is approved for the treatment of pediatric GHD in more than 40 markets, including Canada, Australia, Japan, and EU Member States. With the achievement of these milestones, during the nine months ended September 30, 2023, we recorded revenue of $90 million and during the nine months ended September 30, 2022, we recorded $85.0 million.

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. Pfizer received the exclusive license to commercialize Somatrogon worldwide. In addition, we are eligible to receive regional, tiered gross profit sharing for both Somatrogon and Pfizer's Genotropin® (somatropin) in all global markets, with the U.S. region commencing gross profit sharing in August 2023.

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 September 30, 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, $175.0 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 September 30, 2023	For the three months ended September 30, 2022	For the nine months ended September 30, 2023	For the nine months ended September 30, 2022
Revenue from services:				
Pharmaceutical	$ —	$ —	$ —	$ —
Diagnostics	131,679	142,856	391,100	616,259
Corporate	—	—	—	—
	$ 131,679	$ 142,856	$ 391,100	$ 616,259
Revenue from products:				
Pharmaceutical	$ 40,670	$ 32,388	$ 124,553	$ 104,938
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ 40,670	$ 32,388	$ 124,553	$ 104,938
Revenue from transfer of intellectual property and other:				
Pharmaceutical	$ 6,246	$ 4,500	$ 165,938	$ 97,659
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ 6,246	$ 4,500	$ 165,938	$ 97,659
Operating income (loss):				
Pharmaceutical	$ (25,375)	$ (28,298)	$ 57,210	$ 9,020
Diagnostics	(29,081)	(49,454)	(113,344)	(150,537)
Corporate	(9,951)	(10,068)	(31,841)	(29,467)
	$ (64,407)	$ (87,820)	$ (87,975)	$ (170,984)
Depreciation and amortization:				
Pharmaceutical	$ 17,807	$ 17,840	$ 53,649	$ 50,882
Diagnostics	8,376	10,155	25,666	31,313
Corporate	—	—	—	—
	$ 26,183	$ 27,995	$ 79,315	$ 82,195
Loss from investment in investees:				
Pharmaceutical	$ (20)	$ (43)	$ (99)	$ (359)
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ (20)	$ (43)	$ (99)	$ (359)
Revenues:				
United States	$ 139,043	$ 149,841	$ 462,987	$ 634,754
Ireland	8,654	6,680	121,249	104,318
Chile	16,932	14,347	52,427	46,490
Spain	4,349	4,564	16,427	17,370
Israel	3,155	251	9,388	3,663
Mexico	5,897	3,886	17,447	11,691
Other	565	174	1,666	570
	$ 178,595	$ 179,744	$ 681,591	$ 818,856

(In thousands)	September 30, 2023	December 31, 2022
Assets:		
Pharmaceutical	$ 1,318,982	$ 1,322,531
Diagnostics	649,694	690,504
Corporate	88,004	154,224
	$ 2,056,680	$ 2,167,259
Goodwill:		
Pharmaceutical	$ 311,432	$ 312,826
Diagnostics	283,025	283,025
	$ 594,457	$ 595,851

No customer represented more than 10% of our total consolidated revenue for the nine months ended September 30, 2023 and 2022. As of September 30, 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 September 30, 2023 and December 31, 2022:

(in thousands)	**Classification on the Balance Sheet**	**September 30, 2023**	**December 31, 2022**
Assets			
Operating lease assets	Operating lease right-of-use assets	$ 44,691	$ 38,725
Finance lease assets	Property, plant and equipment, net	10,611	9,898
Liabilities			
Current			
Operating lease liabilities	Current maturities of operating leases	11,267	11,628
Accrued expenses	Current maturities of finance leases	2,931	2,809
Long-term			
Operating lease liabilities	Operating lease liabilities	34,650	27,963
Other long-term liabilities	Finance lease liabilities	$ 7,680	$ 7,089
Weighted average remaining lease term			
Operating leases (in years)		5.8	6.0
Finance leases (in years)		6.1	6.5
Weighted average discount rate			
Operating leases		6.0%	4.4%
Finance leases		4.7%	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 September 30, 2023:

(in thousands)	Operating	Finance
October 1, 2023 through December 31, 2023	$ 3,243	$ 1,076
2024	11,060	3,023
2025	8,939	2,381
2026	7,334	1,738
2027	7,035	976
Thereafter	16,839	1,920
Total undiscounted future minimum lease payments	54,449	11,114
Less: Difference between lease payments and discounted lease liabilities	8,533	503
Total lease liabilities	$ 45,917	$ 10,611

Expense under operating leases and finance leases was $12.0 million and $2.2 million, respectively, for the nine months ended September 30, 2023, which includes $0.9 million of variable lease costs. Expense under operating leases and finance leases was $12.4 million and $2.0 million, respectively, for the nine months ended September 30, 2022, which includes $2.0 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:

	For the nine months ended September 30,	
(in thousands)	2023	2022
Operating cash out flows from operating leases	$ 11,704	$ 12,312
Operating cash out flows from finance leases	327	106
Financing cash out flows from finance leases	1,919	1,020
Total	$ 13,950	$ 13,438

NOTE 17 SUBSEQUENT EVENTS

On October 12, 2023, the Company entered into an E-Commerce Distribution Agreement with NextPlat Corp ("NextPlat"), a global e-commerce provider, in which Dr. Frost owns more than 20% interest. Under the terms of the agreement, NextPlat will launch an OPKO Health-branded online storefront on Alibaba Group Holding Limited Tmall Global e-commerce platform in China featuring an assortment of nutraceutical and veterinary products sold and distributed by OPKO Health Europe SLU, our wholly-owned subsidiary.

On January 2, 2023, ModeX entered into a 10-year office lease agreement commencing in October 2023. ModeX is currently located in Natick, Massachusetts and will relocate to Weston, Massachusetts, upon lease commencement. The new location will have approximately 33,056 square feet of office space. Under the new lease, ModeX has two options to extend the lease term for an additional five years per extension, which would commence upon the expiration of the term on August 1, 2033. Straight-line monthly expense for the lease is approximately $329.5 thousand. ModeX did not have access to the lease premises due to construction by the landlord, and accordingly, we did not record the lease in our Condensed Consolidated Balance Sheet as of September 30, 2023.

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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 have partnered with Pfizer Inc. ("Pfizer") with respect to Somatrogon (hGH-CTP)'s further development. Regulatory applications for Somatrogon (hGH-CTP) have been approved in over 40 markets worldwide, including the United States, EU Member States, Japan, Canada, and Australia 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. In May 2022, we acquired ModeX Therapeutics, Inc. ("ModeX"), a biotechnology company focused on developing innovative multi-specific immune therapies for cancer and infectious disease 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

Foreign Currency Exchange Rates

Approximately 30.7% of revenue for the nine months ended September 30, 2023, and approximately 22.0% of revenue for the nine months ended September 30, 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 affect the translation of revenues and expenses denominated in foreign currencies into USD for purposes of reporting our consolidated financial results. During the nine months ended September 30, 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 $43.1 million and $39.9 million at September 30, 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 seek to 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 September 30, 2023, we had 13 open foreign exchange forward contracts relating to inventory purchases on letters of credit with various amounts maturing monthly through October 2023 with a notional value totaling approximately $0.7 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 SEPTEMBER 30, 2023 AND 2022

Our consolidated loss from operations for the three months ended September 30, 2023 and 2022 was as follows:

	For the three months ended September 30,			
(In thousands)	2023	2022	Change	% Change
Revenues:				
Revenue from services	$ 131,679	$ 142,856	$ (11,177)	(8)%
Revenue from products	40,670	32,388	8,282	26%
Revenue from transfer of intellectual property and other	6,246	4,500	1,746	39%
Total revenues	178,595	179,744	(1,149)	(1)%
Costs and expenses:				
Cost of revenue	130,918	148,445	(17,527)	(12)%
Selling, general and administrative	72,240	79,674	(7,434)	(9)%
Research and development	19,435	18,792	643	3%
Contingent Consideration	(1,125)	(754)	(371)	(49)%
Amortization of intangible assets	21,534	21,407	127	1%
Total costs and expenses	243,002	267,564	(24,562)	(9)%
Loss from operations	$ (64,407)	$ (87,820)	$ 23,413	27%

Diagnostics

(In thousands)	For the three months ended September 30, 2023	2022	Change	% Change
Revenues				
Revenue from services	$ 131,679	$ 142,856	$ (11,177)	(8)%
Total revenues	131,679	142,856	(11,177)	(8)%
Costs and expenses:				
Cost of revenue	106,375	128,182	(21,807)	(17)%
Selling, general and administrative	48,799	57,742	(8,943)	(15)%
Research and development	537	1,437	(900)	(63)%
Amortization of intangible assets	5,049	4,949	100	2%
Total costs and expenses	160,760	192,310	(31,550)	(16)%
Loss from operations	$ (29,081)	$ (49,454)	$ 20,373	41%

Revenue. Revenue from services for the three months ended September 30, 2023 decreased by approximately $11.2 million, a decrease of 8% compared to the three months ended September 30, 2022. The decrease in revenue for the three months ended September 30, 2023, reflects lower demand for COVID-19 testing and lower COVID-19 reimbursement of $9.1 million and $0.9 million, respectively. 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 $6.6 million due to the mix of testing ordered, which was partially offset by an increase in clinical test volume of $5.4 million.

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 of $1.5 million and $5.6 million were recognized for the three months ended September 30, 2023 and 2022, respectively. Revenue adjustments for the three months ended September 30, 2023 ,were mainly due to the composition of patient pay mix and, in 2022, were primarily due to lower COVID-19 test reimbursement estimates.

The composition of revenue from services by payor for the three months ended September 30, 2023 and 2022 was as follows:

(In thousands)	Three months ended September 30, 2023	2022
Healthcare insurers	$ 81,469	$ 58,076
Government payers	19,909	20,151
Client payers	25,906	61,699
Patients	4,395	2,930
Total	$ 131,679	$ 142,856

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 September 30, 2023 decreased $21.8 million, a decrease of 17% compared to the three months ended September 30, 2022. Cost of revenue decreased primarily due to continued cost-reduction initiatives implemented at Bio Reference, a decline in the volume of COVID-19 tests performed during the three months ended September 30, 2023, compared to 2022, and changes in the mix of testing ordered during the period.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2023 and 2022 were $48.8 million and $57.7 million, respectively, a decrease of 15%. Selling, general and administrative expenses decreased primarily due to the continued cost-reduction initiatives implemented at Bio Reference as we strive to return to profitability.

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

Research and Development Expenses	Three months ended September 30,	
	2023	2022
Research and development employee-related expenses	$ 446	$ 821
Other internal research and development expenses	91	616
Total research and development expenses	$ 537	$ 1,437

The decrease in research and development expenses for the three months ended September 30, 2023, was primarily due to the continued cost-reduction initiatives implemented at Bio Reference.

Amortization of intangible assets. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets was $5.1 million and $5.0 million, respectively, for the three months ended September 30, 2023 and 2022.

Pharmaceuticals

(In thousands)	For the three months ended September 30, 2023	2022	Change	% Change
Revenues:				
Revenue from products	$ 40,670	$ 32,388	$ 8,282	26%
Revenue from transfer of intellectual property and other	6,246	4,500	1,746	39%
Total revenues	46,916	36,888	10,028	27%
Costs and expenses:				
Cost of revenue	24,543	20,263	4,280	21%
Selling, general and administrative	13,503	11,610	1,893	16%
Research and development	18,885	17,609	1,276	7%
Contingent Consideration	(1,125)	(754)	(371)	(49)%
Amortization of intangible assets	16,485	16,458	27	0%
Total costs and expenses	72,291	65,186	7,105	11%
Loss from operations	$ (25,375)	$ (28,298)	$ 2,923	10%

Revenue from products. Revenue from products for the three months ended September 30, 2023 and 2022 was $40.7 million and $32.4 million, respectively, an increase of 26%. The increase in revenue from products for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 was attributable to an increase in sales from our international operations, which were positively impacted by foreign exchange fluctuations of approximately $2.9 million, as well as increased sales of *Rayaldee*. Revenue from sales of *Rayaldee* for the three months ended September 30, 2023 and 2022 was $7.3 million and $6.9 million, respectively.

Revenue from transfer of intellectual property and other. For the three months ended September 30, 2023 and 2022, revenue from transfer of intellectual property and other included revenue of $4.9 million and $1.4 million, respectively, of royalty revenue from sales of NGENLA (Somatrogon) in Europe and Japan and does not include an estimate from gross profit in the United States as our partner has not yet provided details post their launch in August 2023. For the three months ended September 30, 2023 and 2022, revenue from transfer of intellectual property and other included $0.9 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 (such financial statements, the "Quarterly Financials")).

Cost of revenue. Cost of revenue for the three months ended September 30, 2023 was $24.5 million, an increase of 21% compared to $20.3 million for the three months ended September 30, 2022, which was attributable to an increase in sales as well as changes in product mix during the period at our international operating companies as well as higher inventory costs partially impacted by unfavorable foreign exchange fluctuations of approximately $2.2 million.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2023 and 2022 were $13.5 million and $11.6 million, respectively, an increase of 16% from the prior period. The increase in selling, general and administrative expenses was due to higher employee-related expenses from our international operations and from higher employee-related expenses related to *Rayaldee*.

Research and development expenses. Research and development expenses for the three months ended September 30, 2023 and 2022 were $18.9 million and $17.6 million, respectively, an increase of 7%. 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 September 30,	
	2023	2022
External expenses:		
Manufacturing expense for biological products	$ 4,060	$ 4,943
Phase 3 studies	744	2,350
Post-marketing studies	184	18
Earlier-stage programs	7,122	3,296
Research and development employee-related expenses	8,822	7,176
Other internal research and development expenses	1,034	798
Third-party grants and funding from collaboration agreements	(3,081)	(972)
Total research and development expenses	$ 18,885	$ 17,609

The increase in research and development expenses for the three months ended September 30, 2023, was primarily due to research expenses at ModeX driven by growth in early-stage programs and an increase in employee-related expenses, 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 September 30, 2023 and 2022 included equity-based compensation expenses of $1.3 million and $0.9 million, respectively.

Contingent consideration. Contingent consideration for the three months ended September 30, 2023 and 2022 was a $1.1 million and $0.8 million reversal of expense, respectively. Contingent consideration for the three months ended September 30, 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 $16.5 million and $16.5 million for the three months ended September 30, 2023 and 2022. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Our indefinite lived IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the FDA, the IPR&D assets will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Corporate

(In thousands)	For the three months ended September 30, 2023	2022	Change	% Change
Costs and expenses:				
Selling, general and administrative	$ 9,938	$ 10,322	$ (384)	(4)%
Research and development	13	(254)	267	105%
Total costs and expenses	9,951	10,068	(117)	(1)%
Loss from operations	$ (9,951)	$ (10,068)	$ 117	1%

Operating loss for our unallocated corporate operations for the three months ended September 30, 2023 and 2022 was $9.9 million and $10.1 million, respectively, and principally reflects general and administrative expenses incurred in connection with our corporate operations. The decrease in operating loss in our unallocated corporate operations for the three months ended September 30, 2023, was as a result of a decrease in employee-related expense partially offset by increases in legal and professional fees.

Other

Interest income. Interest income for the three months ended September 30, 2023 and 2022 was $1.0 million and $0.7 million, respectively. The increase was driven by having higher average cash and investment balances as a result of the cash received related to the sale of GeneDx, as well as increased interest rates.

Interest expense. Interest expense for the three months ended September 30, 2023 and 2022 was $3.4 million and $3.0 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 Quarterly Financials) 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 September 30, 2023 and 2022, was a $0.1 million and $0.4 million reversal of expense, respectively. Derivative expense for the three months ended September 30, 2023 and 2022 was principally related to the change in fair value on foreign currency forward exchange contracts from OPKO Chile.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2023 and 2022 was $11.6 million and $36.7 million of expense, respectively. Other income (expense), net for the three months ended September 30, 2023, and 2022, included $8.3 million and $30.6 million of expense as a result of a decrease in the fair value of our investment in GeneDx Holdings (as defined below). Foreign currency losses of $3.8 million and $5.8 million were the majority of other expenses for the three months ended September 30, 2023, and 2022, respectively.

Income tax benefit (provision). Our income tax benefit (provision) for the three months ended September 30, 2023 and 2022 was a ($6.1 million) provision and a $40.3 million benefit, respectively. For the three months ended September 30, 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, and operating results in tax jurisdictions which do not result in a tax benefit. For the three months ended September 30, 2022, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to due to changes in the company's estimated tax liability, the impact from the IPR&D tax basis difference on deferred attribute realization as a result of the acquisition of ModeX, as well as the relative mix of earnings and losses in the U.S. versus foreign tax jurisdictions, and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have 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 $20.3 thousand and $43.0 thousand for the three months ended September 30, 2023 and 2022, respectively.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023 AND 2022

Our consolidated loss from operations for the nine months ended September 30, 2023 and 2022 was as follows:

(In thousands)	For the nine months ended September 30, 2023	2022	Change	% Change
Revenues:				
Revenue from services	$ 391,100	$ 616,259	$ (225,159)	(37)%
Revenue from products	124,553	104,938	19,615	19%
Revenue from transfer of intellectual property and other	165,938	97,659	68,279	70%
Total revenues	681,591	818,856	(137,265)	(17)%
Costs and expenses:				
Cost of revenue	408,171	586,631	(178,460)	(30)%
Selling, general and administrative	227,676	298,675	(70,999)	(24)%
Research and development	70,199	54,359	15,840	29%
Contingent Consideration	(1,023)	(685)	(338)	(49)%
Amortization of intangible assets	64,543	66,225	(1,682)	(3)%
Gain of sale of assets	—	(15,365)	15,365	100%
Total costs and expenses	769,566	989,840	(220,274)	(22)%
Loss from operations	$ (87,975)	$ (170,984)	$ 83,009	49%

Diagnostics

(In thousands)	For the nine months ended September 30, 2023	2022	Change	% Change
Revenues				
Revenue from services	$ 391,100	$ 616,259	$ (225,159)	(37)%
Total revenues	391,100	616,259	(225,159)	(37)%
Costs and expenses:				
Cost of revenue	333,463	521,221	(187,758)	(36)%
Selling, general and administrative	153,992	231,679	(77,687)	(34)%
Research and development	1,843	10,439	(8,596)	(82)%
Amortization of intangible assets	15,146	18,822	(3,676)	(20)%
Gain of sale of assets	—	(15,365)	15,365	100%
Total costs and expenses	504,444	766,796	(262,352)	(34)%
loss from operations	$ (113,344)	$ (150,537)	$ 37,193	25%

Revenue. Revenue from services for the nine months ended September 30, 2023 decreased by approximately $225.2 million, a decrease of 37% compared to the nine months ended September 30, 2022. The decrease in revenue for the nine months ended September 30, 2023 reflects lower demand for COVID-19 testing and lower COVID-19 reimbursement of $184.7 million and $3.1 million, respectively. The reduction in reimbursement reflects an increase in utilization of antigen point of care diagnostic tests as well as a change in the mix of customers, which have varying contract prices depending on the level of services we provide. For the nine months ended September 30, 2023, clinical test volume increased $30.2 million, while clinical test reimbursement decreased $19.3 million, respectively, as a result of the mix of testing ordered. Furthermore, as a result of our April 2022 sale of GeneDx, genomic test revenues decreased by $49.5 million.

Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as considerations unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when estimating variable consideration in the recognition of revenue in the period the related services are rendered. For the nine months ended September 30, 2023, and 2022, negative revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $19.8 million and $27.8 million, respectively, were recognized. Revenue adjustments for the nine months ended September 30, 2023, and 2022, were primarily due to lower COVID-19 test reimbursement estimates.

The composition of revenue from services by payor for the nine months ended September 30, 2023 and 2022 was as follows:

	Nine months ended September 30,	
(In thousands)	2023	2022
Healthcare insurers	$ 238,934	$ 242,915
Government payers	61,250	74,938
Client payers	77,973	286,423
Patients	12,943	11,983
Total	$ 391,100	$ 616,259

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

Cost of revenue. Cost of revenue for the nine months ended September 30, 2023 decreased $187.8 million, a decrease of 36% compared to the nine months ended September 30, 2022. Cost of revenue decreased primarily due to continued cost-reduction initiatives implemented at BioReference, a decline in the volume of COVID-19 tests performed during the nine months ended September 30, 2023, compared to 2022, and changes in the mix of testing ordered during the period. Furthermore, cost of revenue decreased by $34.9 million as a result of our sale of GeneDx in April 2022.

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2023 and 2022 were $154.0 million and $231.7 million, respectively, a decrease of 34% from the prior period. Selling, general and administrative expenses in our diagnostics segment decreased primarily due to continued cost-reduction initiatives implemented at BioReference as we strive to return to profitability, as well as decreased expenses due to our sale of GeneDx.

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

Research and Development Expenses	Nine months ended September 30,	
	2023	2022
Research and development employee-related expenses	$ 1,292	$ 7,980
Other internal research and development expenses	551	2,459
Total research and development expenses	$ 1,843	$ 10,439

The decrease in research and development expenses for the nine months ended September 30, 2023 was primarily due to the continued cost-reduction initiatives implemented at Bio Reference and partly as a result of the disposition of GeneDx during the second quarter of 2022.

Amortization of intangible assets. Amortization of intangible assets was $15.2 million and $18.8 million, respectively, for the nine months ended September 30, 2023 and 2022. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization expense declined during the nine months ended September 30, 2023 due to the disposition of GeneDx in April 2022 and to acquired intangible assets fully amortized.

Gain on sale of assets. Gain on sale of assets for the nine months ended September 30, 2022, was $15.4 million due to the disposition of GeneDx in April 2022.

Pharmaceuticals

(In thousands)	For the nine months ended September 30, 2023	2022	Change	% Change
Revenues:				
Revenue from products	$ 124,553	$ 104,938	$ 19,615	19%
Revenue from transfer of intellectual property and other	165,938	97,659	68,279	70%
Total revenues	290,491	202,597	87,894	43%
Costs and expenses:				
Cost of revenue	74,708	65,410	9,298	14%
Selling, general and administrative	41,895	36,739	5,156	14%
Research and development	68,304	44,710	23,594	53%
Contingent Consideration	(1,023)	(685)	(338)	(49)%
Amortization of intangible assets	49,397	47,403	1,994	4%
Total costs and expenses	233,281	193,577	39,704	21%
Income from operations	$ 57,210	$ 9,020	$ 48,190	534%

Revenue from products. Revenue from products for nine months ended September 30, 2023 increased $19.6 million an increase of 19% compared to the nine months ended September 30, 2022. The increase in revenue was driven by growing sales from our international operations, which were positively impacted by foreign exchange fluctuations of approximately $5.0 million, as well as increased sales of *Rayaldee*. Revenue from sales of *Rayaldee* for the nine months ended September 30, 2023 and 2022 was $21.7 million and $18.2 million, respectively, an increase of 19.

Revenue from transfer of intellectual property and other. Revenue from transfer of intellectual property and other for the nine months ended September 30, 2023 reflects revenue of $90.0 million triggered by the FDA approval of NGENLA (Somatrogon). For the nine months ended September 30, 2023 and 2022, revenue from transfer of intellectual property and other included revenue of $11.8 million and $1.4 million, respectively, of royalty revenue from sales of NGENLA (Somatrogon) in Europe and Japan and does not include an estimate from gross profit in the United States as our partner has not yet provided details post their launch in August 2023. Furthermore, revenue from transfer of intellectual property and other for the nine months ended September 30, 2023 included $50.0 million from Merck in consideration for the rights granted to Merck under the Merck Agreement (as defined and described in Note 14 to our Quarterly Financials), $7.0 million from Vifor (as described in Note 14 to our Quarterly Financials) triggered by the German price approval for *Rayaldee* and $2.5 million from Nicoya due to Nicoya's submission of the investigational new drug application to China's Center for Drug Evaluation. For the nine months ended September 30, 2022, revenue from transfer of intellectual property and other reflects $85.0 million of regulatory milestone payments from Pfizer due to the commencement of sales of NGENLA (Somatrogon) in Europe and Japan and $3.0 million related to a sales milestone from Vifor.

Cost of revenue. Cost of revenue for the nine months ended September 30, 2023 increased $9.3 million, an increase of 14% compared to the nine months ended September 30, 2022 which was driven by growing sales in our international operations as well as changes in product mix during the period, as well as higher inventory costs compared to the prior period and partially impacted by unfavorable foreign exchange fluctuations of $3.4 million.

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2023 and 2022 were $41.9 million and $36.7 million, respectively, an increase of 14% from the prior year period. The increase in selling, general and administrative expenses was due to higher employee-related expenses from our international operations and from higher employee-related expenses related to *Rayaldee*.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2023 and 2022 were $68.3 million and $44.7 million, respectively, an increase of 53% from the prior year period. 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 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 expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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

Research and Development Expenses	Nine months ended September 30,	
	2023	2022
External expenses:		
Manufacturing expense for biological products	$ 10,039	$ 7,885
Phase III studies	3,871	7,182
Post-marketing studies	342	30
Earlier-stage programs	37,197	9,009
Research and development employee-related expenses	25,584	19,508
Other internal research and development expenses	3,037	2,068
Third-party grants and funding from collaboration agreements	(11,766)	(972)
Total research and development expenses	$ 68,304	$ 44,710

The increase in research and development expenses for the nine months ended September 30, 2023 was primarily due to research expenses at ModeX driven by growth in our early-stage programs and an increase in employee-related expenses, including a $12.5 million payment to Sanofi under the Sanofi In-License Agreement (each as defined and described in Note 14 to our condensed Quarterly Financials), 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 nine months ended September 30, 2023 and 2022 included equity-based compensation expense of $3.1 million and $1.8 million, respectively.

Contingent consideration. Contingent consideration for the nine months ended September 30, 2023 and 2022 was $1.0 million and $0.7 million reversal of expense, respectively. Contingent consideration for the nine months ended September 30, 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 $49.4 million and $47.4 million, respectively, for the nine months ended September 30, 2023 and 2022. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Our indefinite lived IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the FDA, the IPR&D assets will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. 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.

Corporate

(In thousands)	For the nine months ended September 30, 2023	2022	Change	% Change
Costs and expenses:				
Selling, general and administrative	$ 31,789	$ 30,257	$ 1,532	5%
Research and development	52	(790)	842	107%
Total costs and expenses	31,841	29,467	2,374	8%
Loss from operations	$ (31,841)	$ (29,467)	$ (2,374)	(8)%

Operating loss for our unallocated corporate operations for the nine months ended September 30, 2023 and 2022 was $31.8 million and $29.5 million, respectively, and principally reflect general and administrative expenses incurred in connection with our corporate operations. The increase in operating loss for our unallocated corporate operations for the nine months ended September 30, 2023 was primarily due to increase in employee-related and professional expenses, partially offset by a decrease in legal expenses.

Other

Interest income. Interest income for the nine months ended September 30, 2023 and 2022 was $3.1 million and $0.8 million, respectively. The increase is driven by having higher average cash and investment balances as a result of the cash received related to our sale of GeneDx, as well as increased interest rates.

Interest expense. Interest expense for the nine months ended September 30, 2023 and 2022 was $10.1 million and $8.8 million, respectively. Interest expense was principally related to interest incurred on the 2025 Notes, the 2023 Convertible Notes, the 2033 Senior Notes, and BioReference's outstanding debt under the Credit Agreement.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the nine months ended September 30, 2023 and 2022, were $0.8 million of expense and $0.7 million reversal of expense, respectively. Derivative expense for the nine months ended September 30, 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 nine months ended September 30, 2023 and 2022, was $16.1 million and $111.1 million of expense, respectively. Other income (expense), net for the nine months ended September 30, 2023, and 2022, included $13.2 million and $101.8 million, respectively, of expense as a result of a decrease in the fair value of our investment in GeneDx Holdings (as defined below). Foreign currency losses of $1.8 million and $7.6 million were the majority of other expenses for the nine months ended September 30, 2023, and 2022, respectively.

Income tax benefit (provision). Our income tax benefit (provision) for the nine months ended September 30, 2023 and 2022 was ($10.5 million) provision and $46.5 million benefit, respectively. For the nine months ended September 30, 2022, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and operating results in tax jurisdictions which do not result in a tax benefit. For the nine months ended September 30, 2022, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to due to changes in the company's estimated tax liability, the impact from the IPR&D tax basis difference on deferred attribute realization as a result of the acquisition of ModeX, as well as the relative mix of earnings and losses in the U.S. versus foreign tax jurisdictions, and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in certain early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report net losses. Loss from investments in investees was $0.1 million and $0.4 million for the nine months ended September 30, 2023 and 2022, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2023, we had cash and cash equivalents of approximately $138.6 million. Cash used in operations of $10.1 million for the nine months ended September 30, 2023 principally reflects milestone payments of $90.0 million, $7.0 million and $2.5 million from Pfizer, Vifor and Nicoya, respectively, and general and administrative expenses related to our corporate operations and research and development activities. Cash used in investing activities of $16.8 million for the nine months ended September 30, 2023 primarily reflects an investment of $5.0 million in GeneDx Holdings Class A common stock and capital expenditures of $13.3 million. Cash used in financing activities for the nine months ended September 30, 2023 of $7.6 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 September 28, 2023, ModeX was awarded a the BARDA Contract from BARDA (each as defined in Note 14 to our Quarterly Financials), part of the Administration for Strategic Preparedness and Response at the U.S. Department of Health and Human Services, to advance a platform and specific candidates designed to address a range of public health threats in viral infectious diseases. Pursuant to the BARDA Contract, we will receive an initial $59.0 million payment over a five-year period through February 2028 for the development, manufacturing, and execution of a Phase 1 clinical trial for a next-generation MSTAR multispecific antibody with broad neutralizing activity against known variants of SARS-CoV-2. We are eligible to receive up to an additional $109.6 million from BARDA upon achieving particular milestones to develop multispecific antibodies targeting other viral pathogens such as influenza.

In June 2023, the Company and Pfizer announced that the FDA approved NGENLA (Somatrogon), a once-weekly injection to treat pediatric growth hormone deficiency in the United States. With the achievement of the FDA approval milestone, during the nine months ended September 30, 2023, we recorded $90.0 million of revenue under the Restated Pfizer Agreement.

On March 8, 2023, ModeX, the Company (with respect to certain sections), and Merck entered into the Merck Agreement 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, of which $12.5 million was paid to Sanofi during the nine months ended September 30, 2023.

As part of their strategic collaboration, ModeX and Merck have put in place a research plan to manage research and other development activities related to the development of a Vaccine or Product including a joint steering committee to facilitate the research program. As part of the research plan, they will use a third-party contract development and manufacturing organization to carry out such activities unless otherwise agreed. Development costs incurred by ModeX in furtherance of these development activities will be reimbursed by Merck. To date, we have spent $10.8 million of development costs related to the Epstein -Barr Virus, for which Merck has provided reimbursement.

On May 9, 2022, the Company entered into the ModeX Merger Agreement (as defined in Note 1 to our Quarterly Financials), pursuant to which we acquired ModeX. The Company paid the entirety of the $300.0 million purchase price in shares of Common Stock issued to the former stockholders of ModeX. Such 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.

On April 29, 2022, the Company completed the sale of GeneDx. 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 Quarterly Financials). 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. We received 23.1 million shares of Class A Common Stock with respect to Milestone Consideration (as defined in Note 1 to our Quarterly Financials) for the year ended December 31, 2022. As of September 30, 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 $13.0 million.

In April 2022, Pfizer notified OPKO that NGENLA 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.

In February 2018, we issued the 2023 Convertible Notes in the aggregate principal amount of $55.0 million, with an original maturity date in February 2023. 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 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 per share. Interest under the 2023 Convertible Notes accrues 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.

As of September 30, 2023, the total commitments under our Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain were $41.5 million, of which $28.3 million was drawn as of September 30, 2023. At September 30, 2023, the weighted average interest rate on these lines of credit was approximately 7.6%. 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 nine months ended September 30, 2023 was $29.7 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 $50.0 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, 2025 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 September 30, 2023, $11.3 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 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 have received or are eligible to receive up to an additional $275.0 million upon the achievement of certain regulatory milestones, including $90 million triggered by the FDA approval in the US and $85 million due to the commencement of sales of NGENLA (Somatrogon) in Europe and Japan, which we received in 2022. In addition, we are eligible to receive 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 million regulatory milestone payment we recorded in the first quarter of 2023 triggered by the German price approval for *Rayaldee* and $3 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 and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events 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 September 30, 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 approval and success of our products and products in development, particularly our long acting Somatrogon (hGH-CTP) for which we have received approval in over 40 markets, including the United States, 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.

The following table provides information as of September 30, 2023, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining three months ending December 31, 2023	2024	2025	2026	2027	Thereafter	Total
Open purchase orders	$ 42,823	$ 1,167	$ 18	$ —	$ —	$ —	$ 44,008
Operating leases	3,193	10,477	7,960	6,098	5,511	12,678	45,917
Finance leases	823	2,867	2,306	1,719	975	1,921	10,611
2025 and 2023 Convertible Notes	—	—	213,285	—	—	—	213,285
Mortgages and other debts payable	725	1,868	1,532	1,317	1,067	4,691	11,200
Lines of credit	28,347	—	—	—	—	—	28,347
Interest commitments	1,839	6,786	4,486	206	203	615	14,135
Total	$ 77,750	$ 23,165	$ 229,587	$ 9,340	$ 7,756	$ 19,905	$ 367,503

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 $125.0 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 Quarterly Financial and related notes.

RECENT ACCOUNTING PRONOUNCEMENTS

Recently adopted accounting pronouncements.

In December 2022, the European Union member states voted unanimously to adopt a Directive implementing the Pillar 2 (global minimum tax) rules, giving member states until December 31, 2023, to implement the Directive into national legislation. Further details regarding implementing these rules are expected, and if implemented, such reform may increase our tax liabilities and compliance costs and reduce our profitability. Pillar 2 is effective from January 1, 2024, and will be treated as a period cost in future years and will not impact operating results for 2023.

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 30.7% of revenue for the nine months ended September 30, 2023, and approximately 22.0% of revenue for the nine months ended September 30, 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. During the nine months ended September 30, 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 $43.1 million and $39.9 million at September 30, 2023 and December 2022, respectively. For information on such open foreign exchange forward contracts for the three and nine months ended September 30, 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 September 30, 2023, we had cash and cash equivalents of $138.6 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2023 was approximately 3%. As of September 30, 2023, the principal outstanding balances under the Credit Agreement with CB and our Chilean and Spanish lines of credit was $41.5 million in the aggregate at a weighted average interest rate of approximately 7.6%.

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 September 30, 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 September 30, 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. 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.

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 except as described below.

Potential political, economic and military instability in the State of Israel, where we have office, laboratory and manufacturing operations, may adversely affect our results of operations, including as a result of the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them.

We maintain office, laboratory and manufacturing facilities in the State of Israel. Political, economic and military conditions in Israel may directly affect our ability to conduct business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its neighbors. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could adversely affect our operations in Israel. Ongoing and revived hostilities or other Israeli political or economic factors could harm our operations and product development and cause our revenues to decrease.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. The intensity and duration of Israel's current war against Hamas is difficult to predict, as are such war's economic implications on the Company's business and operations in Israel.

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

During the quarter ended September 30, 2023, none of our officers or directors adopted or terminated any contract, instruction or written plan for the purchase or sale of securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement", as defined in Item 408 of Regulation S-K.

Item 6. Exhibits

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 September 30, 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 September 30, 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 September 30, 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 September 30, 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)

+ 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: November 6, 2023

OPKO Health, Inc.

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

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: November 6, 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: November 6, 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 September 30, 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: November 6, 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 September 30, 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: November 6, 2023

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