

**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, 2024.

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  
(State or Other Jurisdiction of  
Incorporation or Organization)

75-2402409  
(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

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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer		Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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, 2024, the registrant had 682,483,029 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, 2023, 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 not generate or sustain profits or cash flow from our laboratory operations or substantial revenue from NGENLA, *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;

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- 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 *Royaldee* 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 for our products and services outside the U.S.;
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations; and
- 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 conflicts in the Middle East

## **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, 2024	December 31, 2023
<b>ASSETS</b>		
Current assets:		
Cash, cash equivalents and current restricted cash	\$ 406,400	\$ 95,881
Accounts receivable, net	106,579	123,379
Inventory, net	59,408	65,697
Other current assets and prepaid expenses	57,249	24,519
Total current assets	629,636	309,476
Property, plant and equipment, net	72,271	75,429
Intangible assets, net	641,396	740,283
In-process research and development	195,000	195,000
Goodwill	535,868	598,260
Investments	100,609	16,082
Operating lease right-of-use assets	62,812	68,088
Other assets	18,511	9,080
Total assets	\$ 2,256,103	\$ 2,011,698
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 62,721	\$ 69,677
Accrued expenses	122,806	90,086
Current maturities of operating leases	12,741	12,996
Current portion of convertible notes	170	—
Current portion of lines of credit and notes payable	13,222	27,293
Total current liabilities	211,660	200,052
Operating lease liabilities	52,057	54,140
Long term portion of convertible notes	178,695	214,325
Senior secured notes	245,358	—
Deferred tax liabilities	128,412	126,773
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	36,504	27,189
Total long-term liabilities	641,026	422,427
Total liabilities	852,686	622,479
Equity:		
Common Stock - \$0.01 par value, 1,250,000,000 shares authorized; 712,283,206 and 781,936,885 shares issued at September 30, 2024 and December 31, 2023, respectively	7,124	7,820
Treasury Stock - 29,800,177, and 8,655,082 shares at September 30, 2024 and December 31, 2023, respectively	(1,791)	(1,791)
Additional paid-in capital	3,516,735	3,433,006
Accumulated other comprehensive loss	(39,614)	(38,030)
Accumulated deficit	(2,079,037)	(2,011,786)
Total shareholders' equity	1,403,417	1,389,219
Total liabilities and equity	\$ 2,256,103	\$ 2,011,698

*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		For the nine months ended	
	September 30,		September 30,	
	2024	2023	2024	2023
<b>Revenues:</b>				
Revenue from services	\$ 121,271	\$ 131,679	\$ 377,557	\$ 391,100
Revenue from products	39,143	40,670	117,675	124,553
Revenue from transfer of intellectual property and other	13,218	6,246	34,272	165,938
<b>Total revenues</b>	<b>173,632</b>	<b>178,595</b>	<b>529,504</b>	<b>681,591</b>
<b>Costs and expenses:</b>				
Cost of service revenue	108,847	106,375	325,798	333,460
Cost of product revenue	24,656	24,543	69,855	74,711
Selling, general and administrative	98,203	72,240	237,191	227,676
Research and development	28,770	19,435	74,789	70,199
Contingent consideration	—	(1,125)	—	(1,023)
Amortization of intangible assets	20,433	21,534	62,290	64,543
Gain on sale of assets	(121,493)	—	(121,493)	—
<b>Total costs and expenses</b>	<b>159,416</b>	<b>243,002</b>	<b>648,430</b>	<b>769,566</b>
<b>Operating income (loss)</b>	<b>14,216</b>	<b>(64,407)</b>	<b>(118,926)</b>	<b>(87,975)</b>
<b>Other income and (expense), net:</b>				
Interest income	2,928	970	4,132	3,077
Interest expense	(17,359)	(3,384)	(33,225)	(10,053)
Fair value changes of derivative instruments, net	(1)	88	(26,161)	(829)
Other income (expense), net	48,636	(11,645)	128,834	(16,045)
<b>Other income (expense), net</b>	<b>34,204</b>	<b>(13,971)</b>	<b>73,580</b>	<b>(23,850)</b>
<b>Income (loss) before income taxes and investment losses</b>	<b>48,420</b>	<b>(78,378)</b>	<b>(45,346)</b>	<b>(111,825)</b>
<b>Income tax provision</b>	<b>(23,527)</b>	<b>(6,075)</b>	<b>(21,898)</b>	<b>(10,456)</b>
<b>Net income (loss) before investment losses</b>	<b>24,893</b>	<b>(84,453)</b>	<b>(67,244)</b>	<b>(122,281)</b>
<b>Loss from investments in investees</b>	<b>(3)</b>	<b>(20)</b>	<b>(7)</b>	<b>(99)</b>
<b>Net income (loss)</b>	<b>\$ 24,890</b>	<b>\$ (84,473)</b>	<b>\$ (67,251)</b>	<b>\$ (122,380)</b>
<b>Income (loss) per share:</b>				
Income (loss) per share, basic	\$ 0.04	\$ (0.11)	\$ (0.10)	\$ (0.16)
Income (loss) per share, diluted	\$ 0.03	\$ (0.11)	\$ (0.10)	\$ (0.16)
Weighted average common shares outstanding, basic	694,622,466	751,525,007	699,675,944	751,716,692
Weighted average common shares outstanding, diluted	998,363,636	751,525,007	699,675,944	751,716,692

*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		For the nine months ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Net income (loss)	\$ 24,890	\$ (84,473)	\$ (67,251)	\$ (122,380)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss)	7,038	(9,554)	(1,585)	(3,173)
Comprehensive income (loss)	<u>\$ 31,928</u>	<u>\$ (94,027)</u>	<u>\$ (68,836)</u>	<u>\$ (125,553)</u>

*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, 2024

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at June 30, 2024	727,176,232	\$ 7,273	(29,799,907)	\$ (1,791)	\$ 3,540,414	\$ (46,652)	\$ (2,103,927)	\$ 1,395,317
Equity-based compensation expense	—	—	—	—	2,784	—	—	2,784
Repurchase of 2029 Convertible Notes	—	—	—	—	(2,853)	—	—	(2,853)
Share repurchase	(14,893,026)	(149)	—	—	(23,610)	—	—	(23,759)
Net income	—	—	—	—	—	—	24,890	24,890
Other comprehensive income	—	—	—	—	—	7,038	—	7,038
Balance at September 30, 2024	712,283,206	\$ 7,124	(29,799,907)	\$ (1,791)	\$ 3,516,735	\$ (39,614)	\$ (2,079,037)	\$ 1,403,417

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2023	781,936,885	\$ 7,820	(8,655,082)	\$ (1,791)	\$ 3,433,006	\$ (38,030)	\$ (2,011,786)	\$ 1,389,219
Equity-based compensation expense	—	—	—	—	7,983	—	—	7,983
Exercise of common stock options and warrants	384,378	4	—	—	(212)	—	—	(208)
2025 Notes	—	—	(21,144,825)	—	—	—	—	—
2029 Convertible Notes	—	—	—	—	151,870	—	—	151,870
Repurchase of 2029 Convertible Notes	—	—	—	—	(2,853)	—	—	(2,853)
Share repurchase	(70,038,057)	(700)	—	—	(73,059)	—	—	(73,759)
Net loss	—	—	—	—	—	—	(67,251)	(67,251)
Other comprehensive loss	—	—	—	—	—	(1,584)	—	(1,584)
Balance at September 30, 2024	712,283,206	\$ 7,124	(29,799,907)	\$ (1,791)	\$ 3,516,735	\$ (39,614)	\$ (2,079,037)	\$ 1,403,417

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	—	—	—	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.

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

	For the nine months ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (67,251)	\$ (122,380)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	74,137	79,315
Non-cash interest	12,753	2,057
Amortization of deferred financing costs	1,328	908
Losses from investments in investees	7	99
Equity-based compensation – employees and non-employees	7,983	8,746
Realized loss (gain) on disposal of fixed assets and sales of equity securities	(9,489)	1,444
Change in fair value of equity securities and derivative instruments	(94,626)	14,406
Loss on conversion convertible senior notes	725	—
Change in fair value of contingent consideration	—	(1,023)
Deferred income tax (benefit) provision	7,695	7,307
Gain on sale of assets	(121,493)	—
Changes in assets and liabilities:		
Accounts receivable, net	15,680	8,741
Inventory, net	6,452	4,082
Other current assets and prepaid expenses	(8,395)	10,220
Other assets	564	(2,666)
Accounts payable	(6,527)	191
Foreign currency measurement	(3,575)	24
Accrued expenses and other liabilities	44,952	(1,374)
Net cash (used in) provided by operating activities	<u>(139,080)</u>	<u>10,097</u>
Cash flows from investing activities:		
Investments in investees	—	(5,000)
Proceeds from sale of equity securities	46,731	364
Purchase of marketable securities	(1,454)	—
Proceeds from the sale of property, plant and equipment	169	1,109
Capital expenditures	(19,597)	(13,253)
Proceeds from LabCorp Sale	210,378	—
Net cash provided by (used in) investing activities	<u>236,227</u>	<u>(16,780)</u>
Cash flows from financing activities:		
Issuance of 3.00% convertible senior notes, net (including related parties)	230,000	—
Issuance of 2044 Notes	250,000	—
Debt issuance costs	(13,385)	—
Share repurchase	(73,759)	—
Proceeds from the exercise of common stock options	(208)	(273)
Repurchase of 2029 Convertible Notes	(4,881)	—
Borrowings on lines of credit	448,459	515,318
Repayments of lines of credit	(465,301)	(519,597)
Redemption of 2025 Notes and 2033 Senior Notes	(146,287)	(3,000)
Net cash provided by (used in) financing activities	<u>224,638</u>	<u>(7,552)</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	2,399	(335)
Net decrease in cash, cash equivalents and restricted cash	<u>324,184</u>	<u>(14,570)</u>
Cash, cash equivalents and restricted cash at beginning of period	<u>95,881</u>	<u>153,191</u>
Cash, cash equivalents and restricted cash at end of period	<u>\$ 420,065</u>	<u>\$ 138,621</u>
<b>SUPPLEMENTAL INFORMATION:</b>		
Interest paid	\$ 12,982	\$ 10,748
Income taxes paid, net of refunds	\$ 3,801	\$ (823)
Assets acquired by finance leases	\$ —	\$ 713
Operating lease right-of-use assets 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	\$ 208	\$ 301
Fair value of shares received related to milestone achieved from GeneDx Holdings	\$ —	\$ 6,689

*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**

OPKO Health, Inc., a Delaware corporation (“OPKO”, the “Company”, “we”, “us”, or “our”) is a diversified healthcare company that seeks to establish industry leading positions in large and rapidly growing medical markets. 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 Somatrogen (hGH-CTP), a once-weekly human growth hormone injection. We have partnered with Pfizer Inc. (“Pfizer”) for the development and commercialization of Somatrogen (hGH-CTP). Regulatory approvals for Somatrogen (hGH-CTP) for the treatment of growth hormone deficiency in children and adolescents have been secured in more than 50 markets, including the United States, European Union (“EU”) Member States, Japan, Canada, and Australia, where it is marketed under the brand name NGENLA®. Through our 2022 acquisition of ModeX Therapeutics, Inc. (“ModeX”), we have expanded our pharmaceutical pipeline with early-stage immune therapies targeting cancer and infectious diseases.

Our diagnostics business, BioReference Health, LLC (“BioReference”), is a highly specialized laboratory in the United States, with a sales and marketing team focused on growth and new product integration, including the 4Kscore® prostate cancer test. BioReference® offers a broad spectrum of diagnostic testing services for oncology, urology (4Kscore), and corrections nationwide, setting new standards with our industry-leading turnaround times. BioReference also provides comprehensive clinical and women’s health testing in New York and New Jersey. Our test offerings are backed by a team of board-certified medical professionals and driven by the latest healthcare guidelines and standards- marketed directly to physicians, geneticists, hospitals, clinics, correctional facilities, and other healthcare providers. On September 16, 2024 we consummated the sale of certain assets of BioReference to Laboratory Corporation of America Holdings (“Labcorp”), as described below.

The Company maintains established, revenue-generating pharmaceutical platforms in Spain, Ireland, Chile, and Mexico, contributing to positive cash flow and facilitating market entry for our development pipeline. In addition to these platforms, we operate a global pharmaceutical development and commercial supply company, a global supply chain operation, and manufacture specialty active pharmaceutical ingredients (API) in Israel through our subsidiary, FineTech.

Our management team possesses extensive industry experience in development, regulatory affairs, and commercialization. Their industry relationships support the identification and pursuit of commercial opportunities. Research and development activities are primarily conducted in facilities located in Weston, Massachusetts, Waterford, Ireland, Kiryat Gat, Israel, and Barcelona, Spain.

On March 27, 2024, the Company and BioReference entered into a definitive agreement with Labcorp (the “Labcorp Asset Purchase Agreement”), pursuant to which Labcorp acquired select assets of BioReference (the “BioReference Transaction”). The BioReference Transaction closed on September 16, 2024, and upon closing, Labcorp paid to the Company aggregate consideration of \$237.5 million in cash, which is subject to certain adjustments as set forth in the Labcorp Asset Purchase Agreement. These assets were part of our diagnostics segment and include BioReference's laboratory testing businesses focused on clinical diagnostics, reproductive health, and women's health across the United States, excluding BioReference's New York and New Jersey operations.

Pursuant to the Labcorp Asset Purchase Agreement, a total of approximately \$23.7 million was withheld at closing and deposited by Labcorp into an escrow account with an escrow account to satisfy potential indemnity claims. The escrow will be released to the Company on the twelve-month anniversary of the closing date, subject to any outstanding or liquidated indemnity claims. The Company recorded the escrow within other current assets on the Condensed Consolidated Balance Sheet.

We recognized a gain of \$121.5 million from the BioReference Transaction for the three and nine months ended September 30, 2024.

**NOTE 2 FOREIGN EXCHANGE RATES****Foreign Currency Exchange Rates**

Approximately 22.3% of our revenue for the nine months ended September 30, 2024, was denominated in currencies other than the U.S. Dollar (USD). This compares to 30.7% for the same period in 2023. Our financial statements are reported in USD; therefore, fluctuations in exchange rates affect the translation of foreign-denominated revenue and expenses. During the nine months ended September 30, 2024 and the year ended December 31, 2023, our most significant currency exchange rate exposures were to the Euro and the Chilean Peso. Gross accumulated currency translation adjustments, recorded as a separate component of shareholders' equity, totaled \$36.2 million and \$34.6 million at September 30, 2024 and December 31, 2023, respectively.

We are subject to foreign currency transaction risk due to fluctuations in exchange rates between the time a transaction is initiated and settled. To mitigate this risk, we use foreign currency forward contracts. These contracts fix an exchange rate, allowing us to offset potential losses (or gains) caused by exchange rate changes at the settlement date. As of September 30, 2024, we held no open foreign exchange forward contracts related to inventory purchases on letters of credit. As of December 31, 2023, we held 52 open foreign exchange forward contracts related to inventory purchases on letters of credit. These contracts matured monthly through January 2024 with a total notional value of approximately \$2.9 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, 2024 are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2024 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, 2023.

*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, cash equivalents and restricted cash.* Cash, cash equivalents and restricted cash 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.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the Condensed Consolidated Balance Sheet to the sum of such amounts in the Condensed Consolidated Statements of Cash Flows:

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 400,079	\$ 95,881
Restricted cash, current	6,321	—
Restricted cash, long-term	13,665	—
Total cash, cash equivalents, and restricted cash shown in the Condensed Consolidated Statements of Cash Flows	<u>\$ 420,065</u>	<u>\$ 95,881</u>

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The Company classifies cash deposits related to letters of credit securing insurance and lease obligations as restricted cash, which is included in other assets, non-current, within the Consolidated Balance Sheet.

*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, 2024 was \$0.6 million and \$1.6 million, respectively. Inventory obsolescence expense for the three and nine months ended September 30, 2023 was \$2.6 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 \$1.4 billion and \$1.5 billion at September 30, 2024 and December 31, 2023, respectively.

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 \$535.9 million and \$598.3 million, respectively, at September 30, 2024 and December 31, 2023.

Net intangible assets other than goodwill were \$836.4 million on each of September 30, 2024, and December 31, 2023, with IPR&D accounting for \$195.0 million on each date. 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 regulatory approval, IPR&D assets are classified as finite-lived intangible assets. These assets are then amortized on a straight-line basis over their estimated useful lives. If a project is abandoned, the associated IPR&D costs are immediately expensed. We also regularly assess finite-lived intangible assets for impairment. This assessment involves comparing the carrying amount of an asset, which is its cost minus accumulated amortization, to its estimated future undiscounted cash flows. If the carrying amount exceeds the estimated future cash flows, an impairment charge is recognized to reflect the difference between the asset's carrying amount and its fair value.

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While we believe our estimates and assumptions used in impairment testing (including for goodwill and IPR&D) are reasonable and reflect those used by market participants, there is a potential risk of material impairment charges. Based on the current financial performance of our diagnostics segment and our Ireland reporting unit (which includes Eirgen and *Rayaldee*), we could be subject to such charges if their future performance deviates from our current estimates and assumptions. For reference, the combined goodwill of these units totaled \$304.9 million and \$367.3 million at September 30, 2024 and December 31, 2023, respectively.

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 \$20.4 million and \$62.3 million for the three and nine months ended September 30, 2024, respectively. Amortization expense was \$21.5 million and \$64.5 million for the three and nine months ended September 30, 2023, respectively.

*Fair value measurements.* The carrying amounts of our cash, cash equivalents, restricted cash, 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, 2024 and December 31, 2023 are predominately carried at fair value. Our debt under the Credit Agreement (as defined below) approximates fair value due to the variable rate of interest applicable to such debt.

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

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

*Derivative financial instruments.* We record derivative financial instruments on our Condensed Consolidated Balance Sheet at their fair value and recognize the changes in the fair value in our Condensed Consolidated Statement of Operations when they occur, the only exception being derivatives that qualify as hedges. For a 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, 2024 and December 31, 2023, 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. In addition, we have determined the value of the embedded derivative liability within the 2029 Convertible 144A Notes (as defined in Note 7) and recorded it at fair value. Refer to Note 7. The changes in the fair value of the embedded derivatives are recognized in the fair value changes of derivatives instruments, net. Refer to Note 9.

*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 \$3.7 million and \$11.9 million for the three and nine months ended September 30, 2024, respectively. Depreciation expense was \$4.8 million and \$14.8 million for the three and nine months ended September 30, 2023, 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, 2024, 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 \$9.9 million related to uncertain tax positions involving income recognition. In connection with an examination of foreign tax returns for the 2015 through 2021 tax years, a foreign taxing authority has issued an income tax assessment of approximately \$246 million (including interest). We are appealing this assessment, as we believe, other than for uncertain tax positions for which we have reserved, the issues are without technical merit. We intend to exhaust all judicial remedies necessary to resolve the matter as necessary, which could be a lengthy process. There can be no assurance that this matter will be resolved in our favor, and an adverse outcome, or any future tax examinations involving similar assertions, could have a material adverse effect on our financial condition, results of operations and cash flows.

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

We apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. For a complete discussion of accounting for Revenues from services, Revenues from products and Revenue from transfer of intellectual property and other, refer to Note 13.

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

While we have receivables due from federal and state governmental agencies, such receivables are not a credit risk because federal and state governments fund the related healthcare programs. Payment is primarily dependent upon submitting appropriate documentation. On September 30, 2024 and December 31, 2023, receivable balances (net of explicit and implicit price concessions) from Medicare and Medicaid were 6.5% and 6.7%, 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, 2024 and December 31, 2023, receivables due from patients represented approximately 2.2% and 2.0%, 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 on each of September 30, 2024 and December 31, 2023. The credit loss expense for the three and nine months ended September 30, 2024, was a reversal expense of \$75.2 thousand and \$67.5 thousand of expense, respectively. The credit loss expense for the three and nine months ended September 30, 2023, was \$98.3 thousand and \$183.4 thousand, respectively.

As of September 30, 2024, accounts receivable included \$1.6 million of revenue earned under the BARDA Contract (as defined in Note 14). As of December 31, 2023, accounts receivable included \$0.6 million under this contract. Refer to Note 13, Government Contract Revenue for further information on government contracts and to Note 14, Strategic Alliances for further information on the BARDA Contract.

*Stock Repurchase Program.* On July 18, 2024, the Company announced that its Board of Directors authorized the repurchase of up to \$100 million shares of Common Stock. Under this program, OPKO may repurchase shares through various methods, including open market purchases, block trades, privately negotiated transactions, and accelerated share repurchases, as well as pursuant to pre-set trading plans meeting the requirements of Rule 10b5-1(c) of the Exchange Act, and otherwise in compliance with applicable laws. The timing and volume of repurchases will depend on market conditions, the Company's capital management, investment opportunities, and other factors. The program does not obligate the Company to repurchase any specific number of shares, has no set expiration date, and may be modified, suspended, or discontinued at the Company's discretion. The Company repurchased 14,893,026 shares for approximately \$23.8 million during the three months ended September 30, 2024.

*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, 2024, we recorded \$2.8 million and \$8.0 million, respectively, of equity-based compensation expense. 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.

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

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

*Segment reporting.* Our chief operating decision-maker ("CODM") is Phillip Frost, M.D., our Chairman and Chief Executive Officer. 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 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 or income taxes. Refer to Note 15.

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



*Foreign currency translation.* The financial statements of certain of our foreign operations are measured using the local currency as the functional currency. The local currency assets and liabilities are generally translated at the rate of exchange to the U.S. dollar on the balance sheet date. The local currency revenues and expenses are translated at average rates of exchange to the U.S. dollar during the reporting periods. Foreign currency transaction gains (losses) have been reflected as a component of Other income (expense), net within the Condensed Consolidated Statement of Operations and foreign currency translation gains (losses) have been included as a component of the Condensed Consolidated Statement of Comprehensive Income (Loss). During the three and nine months ended September 30, 2024, we recorded foreign currency transaction income of \$4.1 million and \$0.1 million, respectively. During the three and nine months ended September 30, 2023, we recorded foreign currency transaction loss of \$3.8 million and \$1.9 million, respectively.

*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.

*Accounting standards yet to be adopted.*

In December 2023, the FASB issued ASU No. 2023-09, “Income Taxes (Topic 740): Improvements to Income Tax Disclosures” (“ASU 2023-09”), which modifies the rules on income tax disclosures to require entities to disclose (i) specific categories in the rate reconciliation, (ii) the income or loss from continuing operations before income tax expense or benefit (separated between domestic and foreign) and (iii) income tax expense or benefit from continuing operations (separated by federal, state and foreign). ASU 2023-09 also requires entities to disclose their income tax payments to international, federal, state, and local jurisdictions, among other changes. The guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. We are currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU No 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (“ASU 2023-07”). ASU 2023-07 enhances disclosures for significant segment expenses for all public entities required to report segment information in accordance with ASC 280. ASC 280 requires a public entity to report for each reportable segment a measure of segment profit or loss that its CODM uses to assess segment performance and to make decisions about resource allocations. The ASU is effective for fiscal years beginning after December 15, 2024 with updates to be applied on a prospective basis with the option to apply the standard retrospectively. Early adoption is permitted. We are currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

*Recently adopted accounting standards.*

In 2021, the Organization for Economic Co-operation and Development (“OECD”) established an inclusive framework on base erosion and profit shifting and agreed on a two-pillar solution (“Pillar Two”) to global taxation, focusing on global profit allocation and a 15% global minimum effective tax rate. On December 15, 2022, the EU member states agreed to implement the OECD’s global minimum tax rate of 15%. The OECD issued Pillar Two model rules and continues to release guidance on these rules. The inclusive framework calls for tax law changes by participating countries to take effect in 2024 and 2025. Various countries have enacted or have announced plans to enact new tax laws to implement the global minimum tax. We considered the applicable tax law changes on Pillar Two implementation in the relevant countries, and there is no material impact to our tax results for the period. We anticipate further legislative activity and administrative guidance in 2024, and will continue to evaluate the impacts of enacted legislation and pending legislation to enact Pillar Two Model Rules in the non-US tax jurisdictions we operate in.

**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) have been 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. We terminated the share lending agreement on January 22, 2024. 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 2029 Convertible Notes, 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 have been antidilutive, no effect is given in the dilutive computation to Common Stock issuable under outstanding options or warrants or the potentially dilutive shares issuable pursuant to the 2029 Convertible Notes, 2033 Senior Notes, the 2023 Convertible Notes and the 2025 Notes. The following table sets forth the computation of basic and diluted income (loss) per share:

(In thousands, except per share data)	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
<b>Numerator</b>				
Net income (loss), basic	\$ 24,890	\$ (84,473)	\$ (67,251)	\$ (122,380)
Add: Interest on 2025 Notes	1	-	-	-
Add: Interest on 2029 Convertible Notes	6,858	-	-	-
Add: Loss on buy back of 2029 Convertible Notes	32	-	-	-
Net income (loss), diluted	\$ 31,781	\$ (84,473)	\$ (67,251)	\$ (122,380)
<b>Denominator</b>				
<u>(Shares in thousands)</u>				
Weighted average common shares outstanding, basic	694,622,466	751,525,007	699,675,944	751,716,692
Effect of dilutive securities:				
Stock options	76,922	-	-	-
Warrants	-	-	-	-
2025 Notes	48,295	-	-	-
2023 Convertible Notes	-	-	-	-
2033 Senior Notes	8,489	-	-	-
2029 Convertible Notes	303,607,464	-	-	-
Dilutive potential shares	303,741,170	-	-	-
Weighted average common shares outstanding, diluted	998,363,636	751,525,007	699,675,944	751,716,692
Loss per share, basic	\$ 0.04	\$ (0.11)	\$ (0.10)	\$ (0.16)
Loss per share, diluted	\$ 0.03	\$ (0.11)	\$ (0.10)	\$ (0.16)

A total of 0 and 83,074,689 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the three months ended September 30, 2024 and 2023, respectively, because their inclusion would have been antidilutive. A total of 286,281,585 and 82,368,398 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2024 and 2023, respectively, because their inclusion would have been antidilutive.

During the three months ended September 30, 2024, no options were exercised and no restricted stock units vested, resulting in the issuance of no shares of Common Stock.

During the nine months ended September 30, 2024, no options were exercised and 549,687 restricted stock units vested, resulting in the issuance of 384,378 shares of Common Stock.

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.

**NOTE 5 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS**

(In thousands)	September 30, 2024	December 31, 2023
<b>Accounts receivable, net:</b>		
Accounts receivable	\$ 108,583	\$ 125,379
Less: allowance for credit losses	(2,004)	(2,000)
	<u>\$ 106,579</u>	<u>\$ 123,379</u>
<b>Inventories, net:</b>		
Consumable supplies	\$ 16,218	\$ 25,864
Finished products	34,206	35,582
Work in-process	2,265	1,731
Raw materials	10,491	8,981
Less: inventory reserve	(3,772)	(6,461)
	<u>\$ 59,408</u>	<u>\$ 65,697</u>
<b>Other current assets and prepaid expenses:</b>		
Escrow receivable	\$ 23,750	\$ —
Taxes recoverable	6,767	4,211
Prepaid expenses	9,572	6,177
Prepaid insurance	6,302	3,848
Other receivables	1,563	2,610
Other	9,295	7,673
	<u>\$ 57,249</u>	<u>\$ 24,519</u>
<b>Intangible assets, net:</b>		
Customer relationships	\$ 258,048	\$ 315,799
Technologies	818,971	831,509
Trade names	49,759	49,758
Covenants not to compete	12,917	12,916
Licenses	6,311	6,205
Product registrations	6,738	6,790
Other	6,052	6,000
Less: accumulated amortization	(517,400)	(488,694)
	<u>\$ 641,396</u>	<u>\$ 740,283</u>
<b>Accrued expenses:</b>		
Employee benefits and severance	\$ 38,474	\$ 28,952
Clinical trials	3,725	7,624
Commitments and contingencies	11,141	8,088
Accrued interest	6,021	2,601
Gross to net provision	6,033	9,420
Inventory received but not invoiced	2,306	1,653
Finance leases short-term	1,855	2,827
Professional fees	4,375	3,470
Taxes payable	15,334	1,384
Royalties	767	1,544
Commissions	1,521	1,822
Other	31,254	20,701
	<u>\$ 122,806</u>	<u>\$ 90,086</u>
<b>Other long-term liabilities:</b>		
Employee severance	\$ 16,284	\$ —
Mortgages and other debts payable	3,529	7,709
Finance leases long-term	4,689	7,274
Contract liabilities	7	7
Other	11,995	12,199
	<u>\$ 36,504</u>	<u>\$ 27,189</u>

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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.

Changes in value of the intangible assets and goodwill during the nine months ended September 30, 2024 and 2023 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, 2024.

(In thousands)	2024				Balance at September 30, 2024
	Gross goodwill at January 1, 2024	Cumulative impairment at January 1	Acquisitions, dispositions and other	Foreign exchange and other	
<b>Pharmaceuticals</b>					
CURNA	\$ 4,827	\$ (4,827)	\$ —	\$ —	\$ —
<i>Rayaldee</i>	84,273	—	—	925	85,198
FineTech	11,698	(11,698)	—	—	—
ModeX	80,260	—	—	—	80,260
OPKO Biologics	139,784	—	—	(0)	139,784
OPKO Chile	3,642	—	—	(81)	3,561
OPKO Health Europe	7,276	—	—	82	7,358
OPKO Mexico	100	(100)	—	—	—
Transition Therapeutics	3,421	(3,421)	—	—	—
<b>Diagnostics</b>					
BioReference	283,025	—	(63,318)	—	219,707
OPKO Diagnostics	17,977	(17,977)	—	—	—
	<u>\$ 636,283</u>	<u>\$ (38,023)</u>	<u>\$ (63,318)</u>	<u>\$ 926</u>	<u>\$ 535,868</u>

**NOTE 6 INVESTMENTS**
*Investments*

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of September 30, 2024 and December 31, 2023:

<u>(in thousands)</u>	As of September 30, 2024		As of December 31, 2023	
	Investment Carrying Value	Underlying Equity in Net Assets	Investment Carrying Value	Underlying Equity in Net Assets
Investment type				
Equity method investments	\$ (0)	\$ 1,782	\$ (0)	\$ 2,942
Variable interest entity, equity method	790	—	796	420
Equity method investments - FV option	92,166		9,786	
Equity securities	130		116	
Equity securities with no readily determinable fair value	7,521		5,382	
Warrants and options	2		2	
Total carrying value of investments	<u>\$ 100,609</u>		<u>\$ 16,082</u>	

*Equity method investments*

Our equity method investments, other than in GeneDx Holdings, as described below, consist of investments in Pharmsynthez (ownership 6%), Cocystal Pharma, Inc. (“COCP”) (2%), Non-Invasive Monitoring Systems, Inc. (“NIMS”) (1%), BioCardia, Inc. (“BioCardia”) (1%), Xenetic Biosciences, Inc. (“Xenetic”) (3%), Zebra Biologics, Inc. (“Zebra”) (29%), and LeaderMed Health Group Limited (“LeaderMed”) (47%). Neovasc, Inc., in which we owned a 0.5% interest, was acquired by Shockwave Medical, Inc. in April 2023. As a result, 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, 2024 were \$66.1 million, \$23.3 million, and \$27.7 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, 2023 were \$85.5 million, \$20.8 million, and \$37.7 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, 2024 and December 31, 2023 was \$0.6 million and \$0.7 million, respectively.

*Equity method investments - Fair value option*

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 GeneDx Holdings acquired our former subsidiary, GeneDx LLC (formerly GeneDx, Inc. “GeneDx”), on April 28, 2022. During the third quarter of 2024, the Company sold 1,386,929 shares of GeneDx common stock at various prices per share for an aggregate of \$46.7 million. As a result of the sale, the Company's total ownership in GeneDx Holdings decreased from 13.61% to 8.1% as of September 30, 2024.

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. This individual was subsequently elected by GeneDx Holdings stockholders and has continued to serve on the board following his re-election in 2024. His term will extend until the GeneDx Holdings annual meeting of stockholders in 2027. We have a shareholder agreement with GeneDx Holdings, pursuant to which we have agreed to vote our shares of GeneDx Holdings common stock in accordance with the recommendation of GeneDx Holdings' 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 position as a shareholder, we are unable to influence GeneDx Holdings' policy-making process.

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We 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, 2024, we recognized \$35.4 million and \$118.6 million in net income related to the change in fair value of our GeneDx Holdings investment, respectively. For the three and nine months ended September 30, 2023, we recognized \$8.3 million and \$19.9 million in net loss related to the change in fair value of our GeneDx Holdings investment, respectively. As of September 30, 2024, the aggregate value of our GeneDx Holdings investment was \$92.2 million based on the quoted market price of the GeneDx Holdings common stock.

### *Investments in equity securities*

Our equity securities consist of investments in VBI Vaccines Inc. (0.00%), ChromaDex Corporation (“ChromaDex”) (0.05%), and Eloxx Pharmaceuticals, Inc. (“Eloxx”) (1%). During the third quarter of 2024, we recorded a \$30 thousand loss from our investment in VBI Vaccines Inc. due to the company filing for bankruptcy. Our equity securities without readily determinable fair value consists of CAMP4 Therapeutics Corporation (“CAMP4”) (2%) and HealthSnap, Inc. (4%). 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 a 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, 2024 and 2023 were as follows:

(in thousands)	For the nine months ended September 30,	
	2024	2023
<b>Equity Securities:</b>		
Net gains and losses recognized during the period on equity securities	\$ 43	\$ (411)
Less: Net gains and losses realized during the period on equity securities	(30)	—
Unrealized net losses recognized during the period on equity securities still held at the reporting date	\$ 13	\$ (411)

### *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, 2024 and December 31, 2023, and warrants to purchase 0.7 million additional shares of InCellDx Inc. 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. 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, 2024 and December 31, 2023. 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, 2024 and December 31, 2023, our debt consisted of the following:

<u>(In thousands)</u>	September 30, 2024	December 31, 2023
2029 Convertible Notes	\$ 178,645	\$ —
2025 Notes	170	143,250
2033 Senior Notes	50	50
2023 Convertible Notes	—	71,025
2044 Notes	245,358	—
JPMorgan Chase Bank line of credit	—	12,671
Chilean and Spanish lines of credit	11,713	12,629
Current portion of notes payable	1,509	1,993
Long term portion of notes payable	3,529	7,727
Total	<u>\$ 440,974</u>	<u>\$ 249,345</u>
Balance sheet captions		
Current portion of convertible notes	\$ 170	\$ —
Long term portion of convertible notes	178,695	214,325
Current portion of lines of credit and notes payable	13,222	27,293
Long Term notes payable included in long-term liabilities	248,887	7,727
Total	<u>\$ 440,974</u>	<u>\$ 249,345</u>

**2044 Note Purchase Agreement**

On July 17, 2024, the Company completed a private offering of \$250 million aggregate principal amount of senior secured notes (the “2044 Notes”), pursuant to a note purchase agreement dated July 17, 2024 (the “2044 Note Purchase Agreement”), by and among the Company, certain purchasers from time to time party thereto, the Company’s wholly owned subsidiaries OPKO Biologics (“OBL”) and EirGen as guarantors (OBL and EirGen collectively, the “2044 Note Guarantors”), and HCR Injection SPV, LLC, as agent.

The 2044 Notes mature on July 17, 2044 and bear interest at the 3-month Secured Overnight Financing Rate (SOFR) subject to a 4.0% per annum floor, plus 7.5% per annum. Interest is payable on the 2044 Notes on a quarterly basis determined by profit share payments received by EirGen pursuant to the profit share arrangement with Pfizer, Inc. (the “Royalty Payments”) set forth in the Restated Pfizer Agreement (as defined and described in Note 14). In the event that the aggregate amount of the Royalty Payments received by EirGen during the quarter preceding any quarterly interest payment date are less than the accrued and unpaid interest payable on such date, the excess interest payable on such date shall be paid-in-kind and added to the outstanding principal amount of the 2044 Notes. The Company will be required to pay the noteholders a 3% exit fee in connection with any repayment in full of the 2044 Notes, whether at maturity or otherwise. In addition, in the event that the Company repays the 2044 Notes in full prior to the maturity date, the Company will be required to pay the noteholders a make whole payment in an amount necessary such that the noteholders shall have received aggregate payments of principal, interest and fees in respect of the 2044 Notes equal to at least 150% of the initial principal amount of the 2044 Notes, in the event that such prepayment shall occur on or prior to July 17, 2029, or 200% of the initial principal amount of the 2044 Notes, in the event that such prepayment shall occur following July 17, 2029. If the 2044 Notes have not been fully repaid by the maturity date, the Company may elect to either repay the unpaid balance of the principal amount in full, together with any accrued and unpaid interest thereon and the 3% exit fee, or elect to transfer 80% of all future Royalty Payments to the agent and the noteholders in satisfaction of the outstanding 2044 Notes. The Company may authorize up to an additional \$50,000,000 in additional 2044 Notes to the purchasers on the same terms and conditions of the initial 2044 Notes. The 2044 Notes are secured by the Royalty Payments, and the 2044 Note Guarantors have guaranteed the obligations under the 2044 Notes by granting a security interest in certain assets of the 2044 Note Guarantors. The 2044 Note Purchase Agreement contains customary terms and covenants, including negative covenants, such as limitations on indebtedness, liens, amendments to certain material contracts and disposition of assets.



*2029 Convertible 144A Notes*

In January 2024, we completed a private offering of \$230.0 million aggregate principal amount of our 3.75% Convertible Senior Notes due 2029 (the “2029 Convertible 144A Notes”) in accordance with the terms of a note purchase agreement (the “144A Note Purchase Agreement”) entered into by and between the Company and J.P. Morgan Securities LLC (the “Initial Purchaser”).

Net proceeds from the 2029 Convertible 144A Notes issuance totaled approximately \$222.0 million after deducting fees and estimated offering expenses payable by us. We allocated approximately \$50.0 million of these net proceeds to repurchase shares of our Common Stock. These repurchases were from purchasers of the 2029 Convertible 144A Notes in privately negotiated transactions effected with or through the Initial Purchaser or its affiliate. The purchase price per share of the Common Stock in these transactions equaled the closing sale price of \$0.9067 per share of Common Stock on January 4, 2024.

Contemporaneously with the closing of the offering of the 2029 Convertible 144A Notes on January 9, 2024, we issued and sold approximately \$71.1 million aggregate principal amount of our 3.75% Convertible Senior Notes due 2029 (the “2029 Convertible Affiliate Notes” and, together with the 2029 Convertible 144A Notes, the “2029 Convertible Notes”) pursuant to the terms of a note purchase agreement entered into on January 4, 2024 (the “Affiliate Note Purchase Agreement”) by and among the Company and certain investors, Frost Gamma Investments Trust, a trust controlled by Dr. Phillip Frost, and Dr. Jane H. Hsiao (collectively, the “Affiliate Purchasers”). Pursuant to the Affiliate Note Purchase Agreement, we issued and sold the 2029 Convertible Affiliate Notes to the Affiliate Purchasers in exchange for the entirety of the \$55.0 million aggregate principal amount of our outstanding 2023 Convertible Notes held by the Affiliate Purchasers, together with approximately \$16.1 million of accrued but unpaid interest thereon.

On January 9th, 2024, we recorded the \$125.6 million value of the embedded derivative liability within the 2029 Convertible Notes as a debt discount. To determine the fair value of this derivative, we employed the Binomial Lattice model. Key inputs and assumptions for this valuation included our common stock price, the derivative's exercise price, risk-free interest rate, volatility, annual coupon rate, and remaining contractual term. We are amortizing the debt discount as non-cash interest expense over the term of the Notes.

From the date the Notes were issued through March 31, 2024, we observed an increase in the market price of our Common Stock which resulted in a \$26.25 million increase in the estimated fair value of our embedded derivatives recorded in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations. Effective April 1, 2024, the conversion option contained in the 2029 Convertible Notes met the classification of an equity component. As a result, we reclassified \$151.9 million of the embedded derivative liability from debt, non-current, to additional paid-in capital section of stockholders' equity on our Condensed Consolidated Balance Sheet.

As of September 30, 2024 the 2029 Convertible 144A Notes are currently convertible. Holders may convert their 2029 Convertible Notes at their option prior to the close of business on the business day immediately preceding September 15, 2028 only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2024 (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 the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable conversion price on each applicable trading day; (2) during the five consecutive business day period after any ten consecutive trading day period (the “convertible note measurement period”) in which the trading price per \$1,000 principal amount of notes for each trading day of the convertible note measurement period was less than 98% of the product of the last reported sale price of our Common Stock and the applicable conversion rate on each such trading day; or (3) upon the occurrence of specified corporate events specified in the indenture governing the 2029 Convertible Notes. On or after September 15, 2028 until the close of business on the business day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing conditions. Upon conversion of a note, 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.

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The conversion rate is initially equal to 869.5652 shares of Common Stock per \$1,000 principal amount of notes (equivalent to an initial conversion price of approximately \$1.15 per share of Common Stock). The conversion rate for the 2029 Convertible Notes will be subject to adjustment upon the occurrence of 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 notes, in certain circumstances we will increase the conversion rate of the 2029 Convertible Notes for a holder who elects to convert its notes in connection with such a corporate event.

We may not redeem the notes prior to the maturity date, and no sinking fund is provided for the notes. If we undergo a fundamental change, holders may require us to purchase the notes in whole or in part for cash at a fundamental change purchase price equal to 100% of the principal amount of the notes to be purchased, *plus* accrued and unpaid interest, if any, to, but excluding, the fundamental change purchase date. The 2029 Convertible Notes are our senior unsecured obligations and rank senior in right of payment to any indebtedness that is expressly subordinated in right of payment to the notes, and equal in right of payment with all of our existing and future unsecured indebtedness that is not so subordinated. The notes are effectively subordinated to all of our existing and future secured indebtedness to the extent of the value of the assets securing such indebtedness and structurally subordinated to all existing and future liabilities of our subsidiaries.

The indenture governing the notes provides for customary events of default which include (subject in certain cases to customary grace and cure periods), among others, the following: nonpayment of principal or interest; breach of covenants or other agreements in the indenture; defaults in failure to pay certain other indebtedness; judgment defaults; and certain events of bankruptcy or insolvency. Generally, if an event of default occurs and is continuing under the indenture, the trustee thereunder or the holders of at least 25% in aggregate principal amount of the notes then outstanding may declare 100% of the principal of and accrued and unpaid interest, if any on all then-outstanding notes to be immediately due and payable. In certain circumstances, we may, for a period of time, elect to pay additional interest on the notes as the sole remedy to holders of the notes in the case of an event of default related to certain failures by us to comply with certain reporting covenants in the indenture.

The following table sets forth information related to the 2029 Convertible Notes which is included in our Condensed Consolidated Balance Sheet as of September 30, 2024:

<u>(In thousands)</u>	2029 convertible notes	Embedded conversion option	Discount	Debt Issuance costs	Total
Balance at December 31, 2023	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of 3.75% 2029 Convertible Notes	301,054	125,620	(125,620)	(8,562)	292,492
Amortization of debt discount and debt issuance costs	—	—	12,585	1,236	13,821
Change in fair value of embedded derivative	—	26,250	—	—	26,250
Reclassification of embedded derivative to equity	—	(151,870)	—	—	(151,870)
Repurchase	(3,500)	—	1,338	114	(2,048)
Balance at September 30, 2024	<u>\$ 297,554</u>	<u>\$ —</u>	<u>\$ (111,697)</u>	<u>\$ (7,212)</u>	<u>\$ 178,645</u>

During the third quarter of 2024, the Company repurchased \$3.5 million in aggregate principal amount of the 2029 Convertible 144A Notes for \$4.8 million in cash. Such convertible debt repurchase resulted in a gain of \$32 thousand, which included unamortized discount of \$1.3 million and debt issuance costs of \$0.1 million.

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### *2025 Convertible Notes*

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.

In May 2021, we entered into an agreement 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”).

Contemporaneously with the closing of our offering of the 2029 Convertible Notes, we repurchased approximately \$144.4 million aggregate principal amount of the 2025 Notes for cash, using \$146.3 million of the net proceeds from our issuance and sale of the 2029 Convertible Notes, following which only \$170 thousand aggregate principal amount of the 2025 Notes remained outstanding.

On January 22, 2024, we terminated our share lending agreement, dated February 4, 2019, with Jefferies Capital Services, LLC (“Share Borrower”). Through this agreement, we had lent the Share Borrower approximately 30 million shares of our Common Stock related to our 2019 issuance of the 2025 Notes. With the termination of this agreement, all remaining borrowed shares of Common Stock have been returned to us and are now held as treasury shares.

### *2023 Convertible Notes*

In February 2018, we issued a series of 5% Convertible Promissory Notes (the “2023 Convertible Notes”) in the aggregate principal amount of \$55.0 million. The original maturity of the 2023 Convertible Notes was five years following the date of issuance. Each holder of a 2023 Convertible Note 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. 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 connection with the closing of the 2029 Convertible Notes offering, the Company issued approximately \$71.1 million aggregate principal amount of its 2029 Convertible Affiliate Notes in exchange for all issued and outstanding 2023 Convertible notes, following which exchange, no 2023 Convertible Notes remained outstanding.

### *2033 Senior Notes*

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 bear interest at the rate of 3.0% per year, payable semiannually on February 1 and August 1 of each year and mature 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 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 2033 Senior Notes in accordance with the indenture governing the 2033 Senior Notes, following which \$50.6 thousand 2033 Senior Notes remained outstanding.

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*JPMorgan Chase Credit Agreement*

In November 2015, BioReference and certain subsidiaries established a credit agreement with JPMorgan Chase Bank, N.A. ("CB") as lender and administrative agent (the "Credit Agreement"). As amended, the Credit Agreement provided for a \$50.0 million secured revolving credit facility, including a \$20.0 million sub-facility for swingline loans and a \$20.0 million sub-facility for letters of credit.

On September 16, 2024, BioReference fully repaid its obligations and terminated the Credit Agreement. BioReference paid approximately \$9.7 million to settle its obligations, incurring no prepayment premium or penalty.

The Credit Agreement had been guaranteed by all of BioReference's domestic subsidiaries and 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. All guarantees and security interests were released together with the termination of the Credit Agreement.

As of December 31, 2023, \$12.7 million was outstanding under the Credit Agreement.

*International Line of Credit Agreements*

The Company has line of credit agreements with twelve other financial institutions as of September 30, 2024, and December 31, 2023, 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)

Lender	Interest rate on borrowings at September 30, 2024	Credit line capacity	Balance Outstanding	
			September 30, 2024	December 31, 2023
JPMorgan Chase	0.00%	\$ —	\$ —	\$ 12,671
Itau Bank	5.50%	1,900	469	1,264
Bank of Chile	6.60%	2,500	711	1,728
BICE Bank	5.50%	2,500	2,433	1,734
Scotiabank	5.00%	5,500	3,060	981
Santander Bank	5.50%	5,000	1,742	450
Security Bank	5.50%	1,400	—	—
Estado Bank	5.50%	4,000	1,355	3,303
BCI Bank	5.00%	2,500	346	1,626
Internacional Bank	5.50%	1,597	1,597	1,197
Consorcio Bank	5.00%	2,000	—	346
Banco De Sabadell	1.75%	558	—	—
Santander Bank	5.36%	558	—	—
Total		\$ 30,013	\$ 11,713	\$ 25,300

At September 30, 2024 and December 31, 2023, the weighted average interest rate on our lines of credit was approximately 5.4% and 7.5%, respectively.

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At September 30, 2024 and December 31, 2023, 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:

<u>(In thousands)</u>	September 30, 2024	December 31, 2023
Current portion of notes payable	\$ 1,509	\$ 1,993
Other long-term liabilities	3,529	7,727
Total	<u>\$ 5,038</u>	<u>\$ 9,720</u>

The notes and other debt mature at various dates ranging from 2024 through 2032, bearing variable interest rates from 0.7% up to 4.5%. The weighted average interest rate on the notes and other debt was 1.8% on September 30, 2024 and 2.9% on December 31, 2023. The notes are partially secured by our office space in Barcelona.

#### NOTE 8 ACCUMULATED OTHER COMPREHENSIVE LOSS

For the nine months ended September 30, 2024, changes in Accumulated other comprehensive loss, net of tax, were as follows:

<u>(In thousands)</u>	Foreign currency translation
Balance at December 31, 2023	\$ (38,030)
Other comprehensive loss	(1,585)
Balance at September 30, 2024	<u>\$ (39,615)</u>

#### 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, 2024, 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). 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 warrants from COCP. In addition, restricted cash collateralized by money market funds is a financial asset measured at fair value as a Level 1 financial instrument under the fair value hierarchy.

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

(In thousands)	Fair value measurements as of September 30, 2024			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
<b>Assets:</b>				
Money market funds	\$ 354,537	\$ —	\$ —	\$ 354,537
Equity securities	130	—	—	130
Equity Method - Fair value option	92,166	—	—	92,166
Common stock options	—	2	—	2
<b>Total assets</b>	<b>\$ 446,833</b>	<b>\$ 2</b>	<b>\$ —</b>	<b>\$ 446,835</b>

(In thousands)	Fair value measurements as of December 31, 2023			
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
<b>Assets:</b>				
Money market funds	\$ 32,404	\$ —	\$ —	\$ 32,404
Equity securities	116	—	—	\$ 116
Equity Method - fair value option	9,786	—	—	9,786
Common stock options/warrants	—	2	—	2
<b>Total assets</b>	<b>\$ 42,306</b>	<b>\$ 2</b>	<b>\$ —</b>	<b>\$ 42,308</b>
<b>Liabilities:</b>				
Forward contracts	—	29	—	29
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ 29</b>	<b>\$ —</b>	<b>\$ 29</b>

The carrying amount and estimated fair value of our 2029 Convertible Notes and 2025 Notes, as well as the applicable fair value hierarchy tiers, are contained in the table below. Additionally, the fair value of the 2029 Convertible Notes and 2025 Notes is determined using inputs other than quoted prices in active markets that are directly observable.

(In thousands)	September 30, 2024				
	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2029 Convertible Notes	\$ 178,645	\$ 396,652	\$ —	\$ 396,652	\$ —
2025 Notes	\$ 170	\$ 170	\$ —	\$ 170	\$ —

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

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The following table reconcile the beginning and ending balances of our Level 3 assets and liabilities as of September 30, 2024.

	September 30, 2024
	Embedded conversion option
(In thousands)	
Balance at December 31, 2023	\$ —
Additions	125,620
Change in fair value:	
Included in results of operations	26,250
Reclassification of embedded derivatives to equity	(151,870)
Balance at September 30, 2024	<u>\$ —</u>

**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, 2024	December 31, 2023
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	\$ 2	\$ 2
Forward contracts	Unrealized losses on forward contracts are recorded in Accrued expenses.	\$ —	\$ (29)

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, 2024 and December 31, 2023, 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, 2024 and 2023:

(In thousands)	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Derivative gain (loss):				
Notes	\$ —	\$ —	\$ (26,250)	\$ —
Common Stock options/warrants	(1)	(37)	1	(27)
Forward contracts	—	125	88	(802)
Total	<u>\$ (1)</u>	<u>\$ 88</u>	<u>\$ (26,161)</u>	<u>\$ (829)</u>

## NOTE 11 RELATED PARTY TRANSACTIONS

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, 2024, we entered into an amendment to our lease agreement with Frost Holdings to decrease the lease space from approximately 29,500 square feet to approximately 26,328 square feet of space. The amended lease provides for payments of approximately \$91 thousand per month in the first year increasing annually to \$103 thousand per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking.

In January 2024, in connection with the closing of the offering of the 2029 Convertible Notes, we issued and sold approximately \$71.1 million aggregate principal amount of the 2029 Convertible Affiliate Notes to the Affiliate Purchasers, in exchange for \$55.0 million aggregate principal amount of the 2023 Convertible Notes, together with approximately \$16.1 million accrued but unpaid interest thereon, held by such Affiliate Purchasers. See Note 7 for additional information.

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 a 20% interest. Under the terms of the agreement, NextPlat has agreed to launch an OPKO Health-branded online storefront on the 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. The Company and NextPlat amended the agreement in October 2024 to extend the term of the agreement to 2026, and permit NextPlat to launch an online storefront on additional e-commerce platforms throughout Asia.

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. Ruen Hui is also 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, 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, 2024, the Company had incurred aggregate expenses of \$1.2 million for services rendered under the Transition Services Agreement. For the three and nine months ended September 30, 2024, the company did not incur expenses for services rendered under the Transaction Services Agreement. As of September 30, 2024, the Company does not have a receivable balance payable to the Company by GeneDx in accordance with the terms of the Transition Services Agreement.



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The Company owns approximately 6% of Pharmsynthez and Pharmsynthez is the largest and controlling shareholder of Xenetic, in which the Company has a 3% ownership interest. Adam Logal, our Senior Vice President and Chief Financial Officer, is a director of Xenetic.

We hold investments in Zebra (ownership 29%), ChromaDex (0.05%), COCP (2%), NIMS (1%), Eloxx (1%), BioCardia (1%) and LeaderMed (47%). Neovasc, Inc., in which we owned a 0.5% interest, 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 a 8.1% 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. See further discussion of our investments in Note 6.

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 \$2.6 million, \$3.3 million, and \$0.3 million, respectively, during the nine months ended September 30, 2024.

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, 2024, we reimbursed and accrued approximately \$0.0 thousand and \$23.9 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. 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.

## 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 and the TX OAG have reached an agreement in principle to settle this matter and are currently negotiating the settlement agreement.

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 effect on our financial condition, results of operations and cash flows.

The Company and BioReference entered into (i) a settlement agreement (the “Settlement Agreement”), effective July 14, 2022, with the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services (“OIG-HHS”), and the Defense Health Agency, acting on behalf of the TRICARE Program (collectively, the “United States”), the Commonwealth of Massachusetts, the State of Connecticut, and the relator identified therein (“Relator”), and (ii) a Corporate Integrity Agreement, effective July 14, 2022 (the “CIA”), with the OIG-HHS, to resolve the investigation and related civil action concerning alleged fee-for-service claims for payment to the Medicare Program, the Medicaid Program, and the TRICARE Program (collectively, the “Federal Health Care Programs”).

Under the Settlement Agreement, the Company and BioReference admitted only to having made payments to certain physicians and physicians’ groups for office space rentals for amounts that exceeded fair market value, and that it did not report or return any such overpayments to the Federal Health Care Programs (the “Covered Conduct”). The Covered Conduct had commenced prior to the Company’s acquisition of BioReference in 2015. With the exception of the Covered Conduct, the Company and BioReference expressly deny the allegations of the Relator as set forth in her civil action. The Company has paid a total of \$10,000,000 plus accrued interest from September 24, 2021 at a rate of 1.5% per annum (the “Settlement Amount”). The Settlement Amount consists of \$9,853,958 payable to the United States, \$141,041 payable to the Commonwealth and \$5,001 payable to Connecticut, in each case plus interest and was paid on July 18, 2022. Conditioned upon payment of the Settlement Amount, the United States, Massachusetts and Connecticut agreed to release the Company and BioReference from any civil or administrative monetarily liability arising from the Covered Conduct. Upon payment of the Settlement Amount and the amount due under a separate agreement with the Relator, the Relator released the Company and BioReference from any and all claims and potential claims. Further, in consideration of the obligations of the Company and BioReference in the Settlement Agreement and the CIA, the OIG-HHS released and refrained from instituting any administrative action seeking to exclude the Company or BioReference from participating in Medicare, Medicaid or other Federal health care programs as a result of the Covered Conduct.

Under the CIA, which has a term of 5 years, BioReference is required to, among other things: (i) maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; (ii) provide management certifications and compliance training and education; (iii) establish written compliance policies and procedures to meet federal health care program requirements; (iv) create procedures designed to ensure compliance with the Anti-Kickback Statute and/or Stark Law; (v) engage an independent review organization to conduct a thorough review of BioReference’s systems, policies, processes and procedures related to certain arrangements; (vi) implement a risk assessment and internal review process; (vii) establish a disclosure program for whistleblowers; and (viii) report or disclose certain events and physician payments. The Company’s or BioReference’s failure to comply with its obligations under the CIA could result in monetary penalties and the exclusion from participation in Federal Health Care Programs. The CIA does not apply to any of the Company’s subsidiaries other than BioReference, and its scope is generally limited to “focus arrangements”, which are those “arrangements” (as defined in the CIA) (i) between BioReference and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value, or (ii) is between BioReference and any physician (or a physician’s immediate family member). Most of these measures have already been implemented at BioReference. Following its acquisition of BioReference, the Company and BioReference implemented robust compliance measures that substantially align with those actions required under the CIA.

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 Prevention 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 and a second amended complaint, both of which were dismissed. Relator then filed an appeal in the U.S. Eleventh Circuit Court of Appeals which is pending before the court following a failed mediation in April 2024. 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, 2024, we were committed to make future purchases for inventory and other items in 2024 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.

*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. For the nine months ended September 30, 2024 and 2023, we recorded \$2.2 million and \$19.8 million of negative revenue adjustments primarily due to the composition of patient pay mix.

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, 2024 and December 31, 2023, we had liabilities of approximately \$4.9 million and \$3.1 million, respectively, within Accrued expenses and Other long-term liabilities related to reimbursements for payor overpayments.

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The composition of revenue from services by payor for the three and nine months ended September 30, 2024 and 2023 was as follows:

(In thousands)	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Healthcare insurers	\$ 76,184	\$ 81,469	\$ 229,600	\$ 238,934
Government payers	20,368	19,909	63,561	61,250
Client payers	20,773	25,906	71,521	77,973
Patients	3,946	4,395	12,875	12,943
Total	<u>\$ 121,271</u>	<u>\$ 131,679</u>	<u>\$ 377,557</u>	<u>\$ 391,100</u>

*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.

*Royaldee* is distributed in the U.S. principally through the retail pharmacy channel, which initiates with the largest wholesalers in the U.S. (collectively, "*Royaldee* Customers"). In addition to distribution agreements with *Royaldee* 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 *Royaldee*.

We recognize revenue for shipments of *Royaldee* 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, 2024, we recognized \$5.8 million and \$19.9 million, respectively, in net product revenue from sales of *Royaldee*. 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 *Royaldee*.

The following table presents an analysis of *Royaldee* product sales allowances and accruals for the three and nine months ended September 30, 2024 and 2023:

(In thousands)	Chargebacks, discounts, rebates and fees				Governmental	Returns	Total
	fees	Governmental	Returns	Total			
Balance at June 30, 2024	\$ 2,743	\$ 5,991	\$ 2,194	\$ 10,928			
Provision related to current period sales	4,005	5,776	317	10,098			
Credits or payments made	(5,058)	(7,013)	(278)	(12,349)			
Balance at September 30, 2024	\$ 1,690	\$ 4,754	\$ 2,233	\$ 8,677			
<i>Total gross Royaldee sales</i>							\$ 15,865
<i>Provision for Royaldee sales allowances and accruals as a percentage of gross Royaldee sales</i>							64%

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(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2023	\$ 2,578	\$ 6,150	\$ 2,192	\$ 10,920
Provision related to current period sales	12,224	16,325	989	29,538
Credits or payments made	(13,112)	(17,721)	(948)	(31,781)
Balance at September 30, 2024	\$ 1,690	\$ 4,754	\$ 2,233	\$ 8,677
<i>Total gross Rayaldee sales</i>				\$ 49,447
<i>Provision for Rayaldee sales allowances and accruals as a percentage of gross Rayaldee sales</i>				60%

(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
<i>Total gross Rayaldee sales</i>				\$ 16,090
<i>Provision for Rayaldee sales allowances and accruals as a percentage of gross Rayaldee sales</i>				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
<i>Total gross Rayaldee sales</i>				\$ 47,940
<i>Provision for Rayaldee sales allowances and accruals as a percentage of gross Rayaldee sales</i>				55%

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.

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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.

**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.

**BARDA Contract:** Revenue from the BARDA Contract is generated under terms that are cost plus fee. We recognize revenue using the incurred costs output method to measure progress. Revenue will only be recognized when research and development services are performed to the extent of actual costs incurred.

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

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

For the three months ended September 30, 2024, revenue from the transfer of intellectual property and other was \$13.2 million, an increase from \$6.2 million for the three months ended September 30, 2023. This increase was primarily attributable to \$5.5 million from the BARDA Contract (as defined and described in Note 14). Gross profit share and royalty payments for NGENLA (Somatrogon) and Pfizer's Genotropin® (Somatropin) also increased to \$7.0 million, compared with \$4.9 million for the same period in 2023.

For the nine months ended September 30, 2024, revenue from the transfer of intellectual property and other decreased to \$34.3 million from \$165.9 million for the nine months ended September 30, 2023. This decrease was primarily due to one-time milestone payments received in 2023, including a \$90.0 million payment related to NGENLA, a \$50.0 million payment from Merck for rights granted under the Merck Agreement, a \$7.0 million payment from VFMCRRP triggered by the German price approval for *Royaldee*, and a \$2.5 million payment from Nicoya upon submission of an investigational new drug application to China's Center for Drug Evaluation. See Note 14 for a description of the arrangements pursuant to which such milestone payments were received. Revenue for the nine months ended September 30, 2024, included \$18.9 million in gross profit share and royalty payments for NGENLA (Somatrogen) and Pfizer's Genotropin® (Somatropin), compared to \$11.8 million in the same period in 2023, as well as \$12.8 million from the BARDA Contract during the 2024 period.

#### **NOTE 14 STRATEGIC ALLIANCES**

##### *Biomedical Advanced Research and Development Authority*

On September 28, 2023, ModeX was awarded a contract (as amended as described below, the "BARDA Contract") by 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. This contract aims to advance a platform and product candidates addressing various public health threats, specifically in viral infectious diseases. The funding enables the research, development, and clinical evaluation of multispecific antibodies based on ModeX's proprietary MSTAR technology. MSTAR is a flexible, plug-and-play platform capable of incorporating multiple independent antibody binding sites into a single molecule, expanding its therapeutic potential and enabling rapid responses to emerging infections, including viral variants like COVID-19, influenza, and other pathogens.

In September 2024, ModeX entered into two amendments (the "BARDA Amendments") to modify the scope and funding of the BARDA Contract. The BARDA Amendments structured the funding thereunder as cost-plus-fixed-fee, which includes a \$26.9 million supplement to further advance the development of COVID-19 multispecific antibodies. This increased funding supports the ongoing development, manufacturing, and execution of a Phase 1 clinical trial for a next-generation MSTAR multispecific antibody with broad neutralizing activity against known SARS-CoV-2 variants. The BARDA Amendments also provided for BARDA's exercise of the option for the development of a multispecific protein antibody for influenza or another pathogen, with \$24.1 million allocated to cover the expanded work under this exercised option. These modifications increased the total value of the BARDA Contract from \$59.0 million to \$110.0 million, with the potential value if BARDA exercises all options thereunder to expand ModeX's services, increasing from \$168.6 million to \$205 million.

As part of the research program, gene-based delivery methods for the multispecific antibodies will be developed using mRNA or DNA vectors to leverage the body's natural protein production processes. BARDA will make periodic progress assessments, and the continuation of the BARDA Contract depends on ModeX's performance, the timeliness and quality of deliverables, and other factors. The BARDA Contract contains customary government contract provisions, including BARDA's right to terminate the contract in its discretion.

The Company evaluated the BARDA Contract under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), and determined that the U.S. government meets the definition of a customer. The scope of the BARDA Contract includes preclinical, clinical, and manufacturing activities, as well as regulatory, quality assurance, management, and administrative activities. The research and development effort will progress in stages covering base and option segments, with ModeX completing specific tasks in each segment.

The Company identified three potential material promises under the BARDA Contract: (i) development of a tetravalent trispecific antibody for COVID-19; (ii) development of a multispecific protein antibody for influenza or another pathogen; and (iii) nucleic acid delivery of a multispecific antibody for influenza or another pathogen. The Company determined the promise to develop a tetravalent trispecific antibody for COVID-19 is a separate performance obligation, as it is distinct within the contract and provides standalone value. Similarly, the exercised option to develop a multispecific protein antibody for influenza or another pathogen is also a separate performance obligation. However, the Company determined that the nucleic acid delivery option does not offer incremental discounts beyond those typically provided for such goods and services, and therefore does not represent a material right. As such, the options in (iii) were not considered performance obligations at the outset of the BARDA Contract.



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The Company concluded that research and development services performed under the BARDA Contract would be recognized as revenue when research and development services are performed to the extent of actual costs incurred including a fixed fee and will be reimbursed by BARDA. Costs incurred represent work performed, which corresponds with, and thereby best depicts, the transfer of control of the research and development to BARDA. Types of contract costs include labor, material, and third-party services. As such, the related BARDA revenue is recognized as revenue from transfer of intellectual property and other within the Company's Consolidated Statements of Operations. For the three and nine months ended September 30, 2024, we recorded \$5.5 million and \$12.8 million in revenue under the BARDA Contract. As of September 30, 2024, the aggregate amount of transaction price allocated to remaining performance obligations, excluding unexercised contract options, was \$96.0 million. We expect to recognize this amount as revenue through February 2028.

### *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 three 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 \$24.5 million of development costs related to the Epstein -Barr Virus, for which Merck has provided 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 Merck 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 oxymodulin 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.

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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 then 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.

The Company was notified that the FDA placed the Dravet clinical trials on hold and CAMP4 subsequently ceased development efforts.

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

#### *VFMCPR*

In May 2016, EirGen and Vifor Fresenius Medical Care Renal Pharma Ltd. ("VFMCPR ") entered into a Development and License Agreement (the "VFMCPR Agreement") for the development and commercialization of *Royaldee* (the "Product") 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 "VFMCPR Territory"), as amended. The license to VFMCPR potentially covers all therapeutic and prophylactic uses of the Product in human patients (the "VFMCPR 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 "VFMCPR Initial Indication").

In January 2023, the German Association of Statutory Health Insurance funds (GKV-SV) granted price approval for *Royaldee*. This triggered a milestone payment of \$7.0 million. In 2022, we recognized a separate milestone payment of \$3.0 million in revenue from the transfer of intellectual property and other for the first sale of *Royaldee* in Europe.

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

Effective May 5, 2020, we entered into an amendment to the VFMCPR Agreement pursuant to which the parties agreed to exclude Mexico, South Korea, the Middle East and all of the countries of Africa from the VFMCPR 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 *Royaldee* 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 \$15 million in regulatory milestones and \$200 million in milestone payments tied to launch, pricing and sales of *Royaldee*, and tiered, double-digit royalties.

We plan to share responsibility with VFMCPR 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 VFMCPR Territory and the commercialization activities outside the VFMCPR Territory and outside the VFMCPR Field in the VFMCPR Territory and VFMCPR will lead the commercialization activities in the VFMCPR Territory and the VFMCPR Field. For the initial development plan, the companies have agreed to certain cost sharing arrangements. VFMCPR will be responsible for all other development costs that VFMCPR considers necessary to develop the Product for the use of the Product for the VFMCPR Initial Indication in the VFMCPR Territory in the VFMCPR Field except as otherwise provided in the VFMCPR Agreement. The first of the clinical studies provided for in the development activities commenced in September 2018.

In connection with the VFMCPR Agreement, the parties entered into a letter agreement pursuant to which EirGen granted to VFMCPR 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, VFMCPR 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. VFMCPR 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, VFMCPR has not exercised the Option.

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

### *Pfizer Inc.*

In December 2014, we entered into an exclusive worldwide agreement with Pfizer for the development and commercialization of our long-acting Somatrogen (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 May 2020, we entered into an amended and restated development and commercialization license with Pfizer, effective January 1, 2020 (the “Restated Pfizer Agreement”), 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.

In June 2023, the FDA approved NGENLA (Somatrogen (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 (Somatrogen). We have also received pricing approvals in Germany and Japan. NGENLA (Somatrogen (hGH-CTP)) is approved for the treatment of pediatric GHD in more than 50 markets, including Canada, Australia, Japan, and EU Member States. With the achievement of these milestones, in 2023 we recorded revenue of \$90 million, and in 2022 we recorded \$85.0 million, in each case under the Restated Pfizer Agreement.

On October 21, 2019, we and Pfizer announced that the global phase 3 trial evaluating Somatrogen 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 Restated Pfizer Agreement 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 Somatrogen worldwide. In addition, we are eligible to receive regional, tiered gross profit sharing for both Somatrogen and Pfizer’s Genotropin® (somatropin) in all global markets, with the U.S. region commencing gross profit sharing in August 2023.

The Restated Pfizer Agreement will remain in effect until the last sale of the licensed product, unless earlier terminated in accordance with its terms. In addition to termination rights for material breach and bankruptcy, Pfizer is permitted to terminate the Restated Pfizer Agreement in its entirety, or with respect to one or more world regions, without cause after a specified notice period. If the Restated 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, 2024 and December 31, 2023, we had no contract liabilities related to the Pfizer Transaction.

The Restated Pfizer Agreement 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 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 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,		For the nine months ended September 30,	
	2024	2023	2024	2023
<b>Revenue from services:</b>				
Pharmaceutical	\$ —	\$ —	\$ —	\$ —
Diagnostics	121,271	131,679	377,557	391,100
Corporate	—	—	—	—
	<u>\$ 121,271</u>	<u>\$ 131,679</u>	<u>\$ 377,557</u>	<u>\$ 391,100</u>
<b>Revenue from products:</b>				
Pharmaceutical	\$ 39,143	\$ 40,670	\$ 117,675	\$ 124,553
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	<u>\$ 39,143</u>	<u>\$ 40,670</u>	<u>\$ 117,675</u>	<u>\$ 124,553</u>
<b>Revenue from transfer of intellectual property and other:</b>				
Pharmaceutical	\$ 13,218	\$ 6,246	\$ 34,272	\$ 165,938
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	<u>\$ 13,218</u>	<u>\$ 6,246</u>	<u>\$ 34,272</u>	<u>\$ 165,938</u>
<b>Operating income (loss):</b>				
Pharmaceutical	\$ (32,196)	\$ (25,375)	\$ (84,697)	\$ 57,210
Diagnostics	58,541	(29,081)	(2,443)	(113,344)
Corporate	(12,129)	(9,951)	(31,786)	(31,841)
	<u>\$ 14,216</u>	<u>\$ (64,407)</u>	<u>\$ (118,926)</u>	<u>\$ (87,975)</u>
<b>Depreciation and amortization:</b>				
Pharmaceutical	\$ 18,043	\$ 17,807	\$ 53,899	\$ 53,649
Diagnostics	6,120	8,376	20,238	25,666
Corporate	—	—	—	—
	<u>\$ 24,163</u>	<u>\$ 26,183</u>	<u>\$ 74,137</u>	<u>\$ 79,315</u>
<b>Loss from investment in investees:</b>				
Pharmaceutical	\$ (3)	\$ (20)	\$ (7)	\$ (99)
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	<u>\$ (3)</u>	<u>\$ (20)</u>	<u>\$ (7)</u>	<u>\$ (99)</u>
<b>Revenues:</b>				
United States	\$ 132,663	\$ 139,043	\$ 410,422	\$ 462,987
Ireland	11,514	8,654	30,579	121,249
Chile	16,576	16,932	49,067	52,427
Spain	6,297	4,349	17,828	16,427
Israel	196	3,155	797	9,388
Mexico	5,630	5,897	18,621	17,447
Other	756	565	2,190	1,666
	<u>\$ 173,632</u>	<u>\$ 178,595</u>	<u>\$ 529,504</u>	<u>\$ 681,591</u>

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<u>(In thousands)</u>	September 30, 2024	December 31, 2023
<b>Assets:</b>		
Pharmaceutical	\$ 1,271,781	\$ 1,331,764
Diagnostics	517,871	630,753
Corporate	466,451	49,181
	<u>\$ 2,256,103</u>	<u>\$ 2,011,698</u>
<b>Goodwill:</b>		
Pharmaceutical	\$ 316,161	\$ 315,235
Diagnostics	219,707	283,025
	<u>\$ 535,868</u>	<u>\$ 598,260</u>

No customer represented more than 10% of our total consolidated revenue for the nine months ended September 30, 2024 and 2023. As of September 30, 2024 and December 31, 2023, 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.

On January 2, 2023, ModeX entered into a 10-year office lease agreement that commenced in October 2023. ModeX was previously located in Natick, Massachusetts and relocated to Weston, Massachusetts, upon lease commencement. The new location is approximately 33,056 square feet of office space. 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 in October 2033. Straight-line monthly expense for the lease is \$243.5 thousand.

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The following table presents the lease balances within the Condensed Consolidated Balance Sheet as of September 30, 2024 and December 31, 2023:

(in thousands)	Classification on the Balance Sheet	September 30, 2024	December 31, 2023
<b>Assets</b>			
Operating lease assets	Operating lease right-of-use assets	\$ 62,812	\$ 68,088
Finance lease assets	Property, plant and equipment, net	6,544	10,101
<b>Liabilities</b>			
Current			
Operating lease liabilities	Current maturities of operating leases	12,741	12,996
Accrued expenses	Current maturities of finance leases	1,855	2,827
Long-term			
Operating lease liabilities	Operating lease liabilities	52,057	54,140
Other long-term liabilities	Finance lease liabilities	\$ 4,689	\$ 7,274
Weighted average remaining lease term			
Operating leases (in years)		6.3	7.1
Finance leases (in years)		7.1	6.2
Weighted average discount rate			
Operating leases		5.3%	5.4%
Finance leases		3.7%	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, 2024:

(in thousands)	Operating	Finance
October 1, 2024 through December 31, 2024	\$ 3,043	\$ 673
2025	11,772	1,813
2026	10,937	1,334
2027	10,775	806
2028	10,785	203
Thereafter	26,534	1,959
Total undiscounted future minimum lease payments	73,846	6,788
Less: Difference between lease payments and discounted lease liabilities	9,048	244
Total lease liabilities	\$ 64,798	\$ 6,544

Expense under operating leases and finance leases was \$15.2 million and \$2.5 million, respectively, for the nine months ended September 30, 2024, which included \$1.5 million of variable lease costs. 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 included \$0.9 million of variable lease costs. Operating lease costs and finance lease costs are included within Operating loss in the Condensed Consolidated Statement of Operations. Short-term lease costs were not material.

Supplemental cash flow information is as follows:

(in thousands)	For the nine months ended September 30,	
	2024	2023
Operating cash out flows from operating leases	\$ 15,101	\$ 11,704
Operating cash out flows from finance leases	354	327
Financing cash out flows from finance leases	2,118	1,919
Total	\$ 17,573	\$ 13,950

## 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, 2023 (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 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. We have partnered with Pfizer Inc. ("Pfizer") for the development and commercialization of *Somatrogon* (hGH-CTP). Regulatory approvals for *Somatrogon* (hGH-CTP) for the treatment of growth hormone deficiency in children and adolescents have been secured in all major markets, including the United States, European Union ("EU") Member States, Japan, Canada, and Australia, where it is marketed under the brand name NGENLA®. Our 2022 acquisition of ModeX Therapeutics, Inc. ("ModeX") has expanded our pharmaceutical pipeline with early-stage immune therapies targeting cancer and infectious diseases.

Our diagnostics business, BioReference Health, LLC ("BioReference"), is a highly specialized laboratory in the United States, with a sales and marketing team focused on growth and new product integration, including the 4Kscore® prostate cancer test. BioReference® offers a broad spectrum of diagnostic testing services for oncology, urology (4Kscore), and corrections nationwide, setting new standards with our industry-leading turnaround times. BioReference also provides comprehensive clinical and women's health testing in New York and New Jersey. Our test offerings are backed by a team of board-certified medical professionals and driven by the latest healthcare guidelines and standards- marketed directly to physicians, geneticists, hospitals, clinics, correctional facilities, and other healthcare providers. On September 16, 2024 we completed an agreement to sell select assets of BioReference to Laboratory Corporation of America Holdings ("Labcorp"), as described below.

The Company maintains established, revenue-generating pharmaceutical platforms in Spain, Ireland, Chile, and Mexico, contributing to positive cash flow and facilitating market entry for our development pipeline. In addition to these platforms, we operate a global pharmaceutical development and commercial supply company, a global supply chain operation, and manufacture specialty active pharmaceutical ingredients (API) in Israel through our subsidiary, FineTech.



## RECENT DEVELOPMENTS

### *ModeX Expands BARDA Collaboration*

In September 2024, ModeX entered into two amendments (the "BARDA Amendments") to modify the scope and funding with our existing contract with 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. The BARDA Amendment increased the total contract value to \$110.0 million, with a potential value of \$205 million if BARDA exercises all options thereunder to expand ModeX's services. The BARDA Amendment includes a \$26.9 million supplement to accelerate the development of our COVID-19 program, including a Phase 1 clinical trial for a next-generation multispecific antibody with broad neutralizing activity against SARS-CoV-2 variants. Additionally, BARDA exercised a \$24.1 million option to initiate the development of a multispecific antibody for influenza or another pathogen.

### *Completion of Disposition of Select BioReference Assets*

On September 16, 2024, the Company completed the sale of certain assets of BioReference (the "BioReference Transaction") to Labcorp. Labcorp paid to the Company aggregate consideration of \$237.5 million in cash, which is subject to certain adjustments as set forth in the Labcorp Asset Purchase Agreement (as defined in Note 1 to our condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q (our "Quarterly Financial Statements")). The assets acquired by Labcorp include BioReference's laboratory testing businesses focused on clinical diagnostics, reproductive health, and women's health across the United States, excluding New York and New Jersey operations. We retained our oncology and urology diagnostic services nationwide. The BioReference assets were formerly part of our diagnostics segment. We recognized a gain of \$121.5 million from the BioReference Transaction for the three and nine months ended September 30, 2024.

### *Stock Repurchase Program*

On July 18, 2024, our Board of Directors authorized the repurchase of up to \$100 million of our Common Stock. Under this program, we may repurchase shares through various methods, including open market purchases, block trades, privately negotiated transactions and accelerated share repurchases, as well as pursuant to pre-set trading plans meeting the requirements of Rule 10b5-1(c) of the Exchange Act, and otherwise in compliance with applicable laws. The timing and volume of repurchases will depend on market conditions, our capital management, investment opportunities, and other factors. The program does not obligate us to repurchase any specific number of shares, has no set expiration date, and may be modified, suspended, or discontinued at our discretion. The Company repurchased 14,893,026 shares for approximately \$23.8 million during the three months ended September 30, 2024.

### *\$250 Million Note Purchase Agreement Secured by NGENLA's Profit Share Payments*

On July 17, 2024, the Company completed a private offering of \$250 million aggregate principal amount of senior secured notes (the "2044 Notes"), pursuant to a note purchase agreement dated July 17, 2024 (the "2044 Note Purchase Agreement"), by and among the Company, certain purchasers party thereto, the Company's wholly-owned subsidiaries OPKO Biologics Limited ("OPKO Biologics") and EirGen Pharma Ltd. ("EirGen") as guarantors (OPKO Biologics and EirGen collectively, the "2044 Note Guarantors"), and HCR Injection SPV, LLC, as agent ("Agent"). The 2044 Notes mature on July 17, 2044 and bear interest at the 3-month Secured Overnight Financing Rate ("SOFR") subject to a 4.0% per annum floor, plus 7.5% per annum. Interest is payable on the 2044 Notes on a quarterly basis determined by profit share payments received by EirGen pursuant to the profit share arrangement with Pfizer, Inc. (the "Royalty Payments") set forth in the Restated Pfizer Agreement (as described in Note 4 to our Quarterly Financials). In the event that the aggregate amount of the Royalty Payments received by EirGen during the quarter preceding any quarterly interest payment date are less than the accrued and unpaid interest payable on such date, the excess interest payable on such date shall be paid-in-kind and added to the outstanding principal amount of the 2044 Notes. The Company will be required to pay the noteholders a 3% exit fee in connection with any repayment in full of the 2044 Notes, whether at maturity or otherwise. In addition, in the event that the Company repays the 2044 Notes in full prior to the maturity date, the Company will be required to pay the noteholders a make whole payment in an amount necessary such that the noteholders shall have received aggregate payments of principal, interest and fees in respect of the 2044 Notes equal to at least 150% of the initial principal amount of the 2044 Notes, in the event that such prepayment shall occur on or prior to July 17, 2029, or 200% of the initial principal amount of the 2044 Notes, in the event that such prepayment shall occur following July 17, 2029. The Company may authorize up to an additional \$50,000,000 in additional 2044 Notes to the purchasers on the same terms and conditions of the initial 2044 Notes.

*Offering of 3.75% Convertible Senior Notes due 2029*

In January 2024, we completed a private offering of \$230.0 million aggregate principal amount of our 3.75% Convertible Senior Notes due 2029 (the “2029 Convertible 144A Notes”) in accordance with the terms of a note purchase agreement (the “144A Note Purchase Agreement”) entered into by and between the Company and J.P. Morgan Securities LLC (the “Initial Purchaser”). The \$230.0 million aggregate principal amount of 2029 Convertible 144A Notes included \$30.0 million aggregate principal amount of 2029 Convertible 144A Notes purchased on the Closing Date by the Initial Purchaser in accordance with its overallotment option.

Net proceeds from the 2029 Convertible 144A Notes issuance totaled approximately \$222.0 million after deducting fees and estimated offering expenses payable by us. We allocated approximately \$50.0 million of these net proceeds to repurchase shares of our Common Stock. These repurchases were from purchasers of the 2029 Convertible 144A Notes in privately negotiated transactions effected with or through the Initial Purchaser or its affiliate. The purchase price per share of the Common Stock in these transactions equaled the closing sale price of \$0.9067 per share of Common Stock on January 4, 2024.

Contemporaneously with the closing of the offering of the 2029 Convertible Notes on January 9, 2024, we issued and sold approximately \$71.1 million aggregate principal amount of our 3.75% Convertible Senior Notes due 2029 (the “2029 Convertible Affiliate Notes” and, together with the 2029 Convertible 144A Notes, the “2029 Convertible Notes”) pursuant to the terms of a note purchase agreement entered into on January 4, 2024 (the “Affiliate Note Purchase Agreement”) by and among the Company and certain investors including, Frost Gamma Investments Trust, a trust controlled by Phillip Frost, M.D., our Chairman and Chief Executive Officer, and Jane H. Hsiao, Ph.D., MBA, our Vice-Chairman and Chief Technical Officer (collectively, the “Affiliate Purchasers”). Pursuant to the Affiliate Note Purchase Agreement, we issued and sold the 2029 Convertible Affiliate Notes to the Affiliate Purchasers in exchange for the entirety of the \$55.0 million aggregate principal amount of our outstanding 2023 Convertible Notes held by the affiliate Purchasers, together with approximately \$16.1 million of accrued but unpaid interest thereon.

Furthermore, in connection with the closing of our offering of the 2029 Convertible Notes, we repurchased approximately \$144.4 million aggregate principal amount of the 2025 Notes for cash, using \$146.3 million of the net proceeds from our issuance and sale of the 2029 Convertible 144A Notes.

*Termination of Share Lending Agreement*

On January 22, 2024, we terminated our share lending agreement, dated February 4, 2019, with Jefferies Capital Services, LLC (“Share Borrower”). Through this agreement, we had lent the Share Borrower approximately 30 million shares of our common stock related to our 2019 issuance of the \$200.0 million in 2025 Notes. We had since reduced the number of outstanding borrowed shares by approximately 8.313 million. With the termination of this agreement, all remaining shares have been returned to us and are now held as treasury shares.

**RESULTS OF OPERATIONS****Foreign Currency Exchange Rates**

Approximately 22.3% of our revenue for the nine months ended September 30, 2024, was denominated in currencies other than the U.S. Dollar (USD). This compares to 30.7% for the same period in 2023. Our financial statements are reported in USD; therefore, fluctuations in exchange rates affect the translation of foreign-denominated revenue and expenses. During the second quarter of 2024 and the year ended December 31, 2023, our most significant currency exchange rate exposures were to the Euro and the Chilean Peso. Gross accumulated currency translation adjustments, recorded as a separate component of shareholders' equity, totaled \$36.2 million and \$34.6 million at September 30, 2024 and December 31, 2023, respectively.

We are subject to foreign currency transaction risk due to fluctuations in exchange rates between the time a transaction is initiated and settled. To mitigate this risk, we use foreign currency forward contracts. These contracts fix an exchange rate, allowing us to offset potential losses (or gains) caused by exchange rate changes at the settlement date. As of September 30, 2024, we held no open foreign exchange forward contracts related to inventory purchases on letters of credit. As of December 31, 2023, we held 52 open foreign exchange forward contracts related to inventory purchases on letters of credit. These contracts matured monthly through January 2024 with a total notional value of approximately \$2.9 million.

**FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023**

Our consolidated (loss) income from operations for the three months ended September 30, 2024 and 2023 was as follows:

(In thousands)	For the three months ended		Change	% Change
	2024	2023		
<b>Revenues:</b>				
Revenue from services	\$ 121,271	\$ 131,679	\$ (10,408)	(8)%
Revenue from products	39,143	40,670	(1,527)	(4)%
Revenue from transfer of intellectual property and other	13,218	6,246	6,972	112%
<b>Total revenues</b>	<b>173,632</b>	<b>178,595</b>	<b>(4,963)</b>	<b>(3)%</b>
<b>Costs and expenses:</b>				
Cost of revenue	133,503	130,918	2,585	2%
Selling, general and administrative	98,203	72,240	25,963	36%
Research and development	28,770	19,435	9,335	48%
Contingent consideration	—	(1,125)	1,125	100%
Amortization of intangible assets	20,433	21,534	(1,101)	(5)%
Gain on sale of assets	(121,493)	—	(121,493)	(100)%
<b>Total costs and expenses</b>	<b>159,416</b>	<b>243,002</b>	<b>(83,586)</b>	<b>(34)%</b>
<b>Income (loss) from operations</b>	<b>\$ 14,216</b>	<b>\$ (64,407)</b>	<b>\$ 78,623</b>	<b>122%</b>

**Diagnostics**

(In thousands)	For the three months ended			
	September 30,		Change	% Change
	2024	2023		
<b>Revenues</b>				
Revenue from services	\$ 121,271	\$ 131,679	\$ (10,408)	(8)%
Total revenues	121,271	131,679	(10,408)	(8)%
<b>Costs and expenses:</b>				
Cost of revenue	108,846	106,375	2,471	2%
Selling, general and administrative	70,946	48,799	22,147	45%
Research and development	493	537	(44)	(8)%
Amortization of intangible assets	3,938	5,049	(1,111)	(22)%
Gain on sale of assets	(121,493)	—	(121,493)	(100)%
Total costs and expenses	62,730	160,760	(98,030)	(61)%
Income (loss) from operations	\$ 58,541	\$ (29,081)	\$ 87,622	301%

*Revenue.* Revenue from services for the three months ended September 30, 2024 decreased by approximately \$10.4 million, a decrease of 7.9% compared to the same period in 2023. This decrease was primarily due to a \$2.0 million reduction in clinical test reimbursement rates and an \$8.4 million decrease in clinical test volume, of which \$3.3 million was attributable to the BioReference Transaction.

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 three months ended September 30, 2024 and 2023, we recorded \$0.7 million and \$1.5 million, respectively. These adjustments reflect changes in estimated implicit price concessions for services provided in prior periods, primarily due to shifts in the composition of our client mix

The composition of revenue from services by payor for the three months ended September 30, 2024 and 2023 was as follows:

(In thousands)	Three months ended September 30,	
	2024	2023
Healthcare insurers	\$ 76,184	\$ 81,469
Government payers	20,368	19,909
Client payers	20,773	25,906
Patients	3,946	4,395
Total	\$ 121,271	\$ 131,679

*Cost of revenue.* Cost of revenue for the three months ended September 30, 2024 increased \$2.5 million, an increase of 2.3% compared to the three months ended September 30, 2023. The increase is primarily due to \$4.2 million in accruals set aside to cover volume shortfalls on contracts as a result of the Labcorp transaction.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for the three months ended September 30, 2024 and 2023 were \$71.0 million and \$48.8 million, respectively, representing an increase of 45.4% from the prior period. The increase in selling, general and administrative expenses was primarily due to severance expense of \$26.3 million, offset by a decrease in employee-related expenses, reflecting continued cost-reduction initiatives.

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

Research and Development Expenses (In thousands)	Three months ended September 30,	
	2024	2023
Research and development employee-related expenses	\$ 161	\$ 446
Other internal research and development expenses	332	91
<b>Total research and development expenses</b>	<b>\$ 493</b>	<b>\$ 537</b>

The decrease in research and development expenses for the three months ended September 30, 2024 as compared to 2023 was primarily due to a decrease in employee-related expenses as a result of the continued cost-reduction initiatives implemented at BioReference.

*Amortization of intangible assets.* Amortization of intangible assets was \$3.9 million and \$5.1 million, respectively, for the three months ended September 30, 2024 and 2023. The decrease is primarily attributable to the BioReference Transaction, which impacted the amount of amortizable intangible assets.

*Gain on sale of assets.* Gain on sale of assets for the three months ended September 30, 2024, was \$121.5 million which reflects the gain on sale from the BioReference Transaction.

### Pharmaceuticals

(In thousands)	For the three months ended September 30,			
	2024	2023	Change	% Change
<b>Revenues:</b>				
Revenue from products	\$ 39,143	\$ 40,670	\$ (1,527)	(4)%
Revenue from transfer of intellectual property and other	13,218	6,246	6,972	112%
<b>Total revenues</b>	<b>52,361</b>	<b>46,916</b>	<b>5,445</b>	<b>12%</b>
<b>Costs and expenses:</b>				
Cost of revenue	24,657	24,543	114	0%
Selling, general and administrative	15,161	13,503	1,658	12%
Research and development	28,244	18,885	9,359	50%
Contingent consideration	—	(1,125)	1,125	100%
Amortization of intangible assets	16,495	16,485	10	0%
<b>Total costs and expenses</b>	<b>84,557</b>	<b>72,291</b>	<b>12,266</b>	<b>17%</b>
Loss from operations	\$ (32,196)	\$ (25,375)	\$ (6,821)	(27)%

*Revenue from products.* Revenue from products for the three months ended September 30, 2024 decreased \$1.5 million or 3.8%, compared to the three months ended September 30, 2023. This decrease was largely attributable to lower Rayaldee sales, which generated \$5.8 million of revenue for the three months ended September 30, 2024, compared to \$7.3 million for the same period in 2023. In addition, demand for our products in international operations increased, foreign currency fluctuations also negatively impacted revenue.

*Revenue from transfer of intellectual property and other.* For the three months ended September 30, 2024, revenue from the transfer of intellectual property and other was \$13.2 million compared to \$6.3 million for the prior year period. This increase was primarily attributable to \$5.5 million from the BARDA Contract (as defined and described in Note 14 to our Quarterly Financials). Gross profit share and royalty payments for NGENLA (Somatrogen) and Pfizer's Genotropin® (Somatropin) also increased to \$7.0 million, compared with \$4.9 million for the same period in 2023.

*Cost of revenue.* Cost of revenue for the three months ended September 30, 2024 increased \$0.1 million, an increase of 0.5%, compared to the three months ended September 30, 2023. Cost of revenue increased primarily due to a shift in product mix offset by favorable foreign currency exchange, which had a positive impact on cost of revenue, reducing it by \$1.5 million.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for the three months ended September 30, 2024 and 2023 were \$15.2 million and \$13.5 million, respectively, an increase of 12.3% from the prior year period. This increase was primarily driven by higher professional fees. Additionally, employee-related expenses also contributed to the increase in SG&A in our international operations.

*Research and development expenses.* Research and development expenses for the three months ended September 30, 2024 and 2023 were \$28.2 million and \$18.9 million, respectively, an increase of 49.6% 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 (In thousands)	Three months ended September 30,	
	2024	2023
External expenses:		
Manufacturing expense for biological products	\$ 9,355	\$ 4,060
Phase 3 studies	684	744
Post-marketing studies	226	184
Earlier-stage programs	7,481	7,122
Research and development employee-related expenses	10,276	8,822
Other internal research and development expenses	2,031	1,034
Third-party grants and funding from collaboration agreements	(1,809)	(3,081)
Total research and development expenses	<u>\$ 28,244</u>	<u>\$ 18,885</u>

Research and development expenses for the three months ended September 30, 2024 increased primarily due to higher expenses at ModeX. This increase was driven by a combination of factors, including growth in our BARDA collaboration, advancements and expansion in our early-stage programs, and higher employee-related expenses.

*Contingent consideration.* Contingent consideration for the three months ended September 30, 2024 was zero, as compared to \$1.1 million reversal of expense for the three months ended September 30, 2023. Contingent consideration for the three months ended September 30, 2023 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 2013.

*Amortization of intangible assets.* Amortization of intangible assets was \$16.5 million and \$16.5 million, respectively, for the three months ended September 30, 2024 and 2023. 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. The assets will be amortized on a straight-line basis over their estimated useful life of approximately 12 years.

## Corporate

(In thousands)	For the three months ended September 30,			
	2024	2023	Change	% Change
<b>Costs and expenses:</b>				
Selling, general and administrative	\$ 12,096	\$ 9,938	\$ 2,158	22%
Research and development	33	13	20	154%
Total costs and expenses	12,129	9,951	2,178	22%
Loss from operations	\$ (12,129)	\$ (9,951)	\$ (2,178)	(22)%

Operating loss for our unallocated corporate operations for the three months ended September 30, 2024 and 2023 was \$12.1 million and \$10.0 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 was primarily due to an increase in employee-related expenses.

## Other

*Interest income.* Interest income for the three months ended September 30, 2024 and 2023 was \$2.9 million and \$1.0 million, respectively. The increase in interest income is driven by the yield obtained in our larger cash investment.

*Interest expense.* Interest expense increased to \$17.4 million for the three months ended September 30, 2024, compared to \$3.4 million in the same period of 2023. The increase in interest expense was primarily driven by \$14.6 million interest incurred on the 2029 Convertible Notes and the 2044 Notes, including amortization of deferred financing and debt issuance costs. This increase was partially offset by the extinguishment of our outstanding 2023 Convertible Notes and the repurchase of the 2025 Convertible Notes.

*Fair value changes of derivative instruments, net.* Fair value changes of derivative instruments, net for the three months ended September 30, 2024 and 2023, was \$1.0 thousand and \$88.0 thousand of expense, respectively. Derivative expense was principally related to foreign currency forward exchange contracts at OPKO Chile.

*Other income (expense), net.* Other income (expense), net for the three months ended September 30, 2024, resulted in \$48.6 million of income compared to \$11.7 million of expense for the 2023 period. This was primarily driven by changes in the fair value of our investment in GeneDx Holdings (as defined in Note 6 to our Quarterly Financials). During the three months ended September 30, 2024, we recorded income of \$35.4 million related to this investment, compared to an expense of \$8.3 million in the prior-year period. Additionally, we realized a gain of \$10.5 million from the sale of 1,386,929 shares of GeneDx during the three months ended September 30, 2024. Foreign currency income of \$4.1 million was recorded for the 2024 period, compared with a \$3.8 million expense in the 2023 period.

*Income tax provision.* Our income tax provision for the three months ended September 30, 2024 and 2023 was \$23.5 million and \$6.1 million, respectively. This significant increase was primarily driven by a discrete expense related to the BioReference Transaction. While the U.S. federal statutory rate is 21%, our effective tax rate for the three months ended September 30, 2024 and 2023 differed from this rate 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.

*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 an equity holder. 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 \$3.0 thousand and \$20.0 thousand for the three months ended September 30, 2024 and 2023, respectively.

**FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023**

Our consolidated loss from operations for the nine months ended September 30, 2024 and 2023 was as follows:

<u>(In thousands)</u>	For the nine months ended September 30,		Change	% Change
	2024	2023		
<b>Revenues:</b>				
Revenue from services	\$ 377,557	\$ 391,100	\$ (13,543)	(3)%
Revenue from products	117,675	124,553	(6,878)	(6)%
Revenue from transfer of intellectual property and other	34,272	165,938	(131,666)	(79)%
<b>Total revenues</b>	<b>529,504</b>	<b>681,591</b>	<b>(152,087)</b>	<b>(22)%</b>
<b>Costs and expenses:</b>				
Cost of revenue	395,653	408,171	(12,518)	(3)%
Selling, general and administrative	237,191	227,676	9,515	4%
Research and development	74,789	70,199	4,590	7%
Contingent consideration	—	(1,023)	1,023	100%
Amortization of intangible assets	62,290	64,543	(2,253)	(3)%
Gain on sale of assets	(121,493)	—	(121,493)	(100)%
<b>Total costs and expenses</b>	<b>648,430</b>	<b>769,566</b>	<b>(121,136)</b>	<b>(16)%</b>
<b>Loss from operations</b>	<b>\$ (118,926)</b>	<b>\$ (87,975)</b>	<b>\$ (30,951)</b>	<b>(35)%</b>

***Diagnostics***

<u>(In thousands)</u>	For the nine months ended September 30,		Change	% Change
	2024	2023		
<b>Revenues</b>				
Revenue from services	\$ 377,557	\$ 391,100	\$ (13,543)	(3)%
<b>Total revenues</b>	<b>377,557</b>	<b>391,100</b>	<b>(13,543)</b>	<b>(3)%</b>
<b>Costs and expenses:</b>				
Cost of revenue	325,797	333,463	(7,666)	(2)%
Selling, general and administrative	161,208	153,992	7,216	5%
Research and development	1,545	1,843	(298)	(16)%
Amortization of intangible assets	12,943	15,146	(2,203)	(15)%
Gain on sale of assets	(121,493)	—	(121,493)	(100)%
<b>Total costs and expenses</b>	<b>380,000</b>	<b>504,444</b>	<b>(124,444)</b>	<b>(25)%</b>
<b>Loss from operations</b>	<b>\$ (2,443)</b>	<b>\$ (113,344)</b>	<b>\$ 110,901</b>	<b>98%</b>

*Revenue.* Revenue from services for the nine months ended September 30, 2024 decreased by approximately \$13.5 million, a decrease of 3.5% compared to the nine months ended September 30, 2023. This decrease was primarily due to a \$6.5 million reduction in clinical test reimbursement rates and an \$7.0 million decrease in clinical test volume, of which \$3.3 million was attributable to the BioReference Transaction.

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, 2024 and 2023, we recorded \$2.2 million and \$19.8 million, respectively, of negative revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods mainly due to the composition of patient pay mix.



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The composition of revenue from services by payor for the nine months ended September 30, 2024 and 2023 was as follows:

(In thousands)	Nine months ended September 30,	
	2024	2023
Healthcare insurers	\$ 229,600	\$ 238,934
Government payers	63,561	61,250
Client payers	71,521	77,973
Patients	12,875	12,943
Total	\$ 377,557	\$ 391,100

*Cost of revenue.* Cost of revenue for the nine months ended September 30, 2024 decreased \$7.7 million, a decrease of 2.3% compared to the nine months ended September 30, 2023. Cost of revenue decreased primarily due to lower employee headcount, reflecting our continued cost-reduction initiatives implemented at BioReference, changes in the mix of testing ordered during the period, and by a decrease in consumption reflecting the timing of the BioReference Transaction.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for the nine months ended September 30, 2024 and 2023 were \$161.2 million and \$154.0 million, respectively, representing a decrease of 4.7% from the prior period. The increase in selling, general and administrative expenses was primarily due to severance expense of \$26.3 million, offset by a decrease in employee-related expenses, reflecting continued cost-reduction initiatives.

*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,	
	2024	2023
Research and development employee-related expenses	\$ 1,006	\$ 1,292
Other internal research and development expenses	539	551
Total research and development expenses	\$ 1,545	\$ 1,843

The decrease in research and development expenses for the nine months ended September 30, 2024 was primarily due to a decrease in employee-related expenses as a result of the continued cost-reduction initiatives implemented at BioReference.

*Amortization of intangible assets.* Amortization of intangible assets was \$12.9 million and \$15.2 million, respectively, for the nine months ended September 30, 2024 and 2023. The decrease is primarily attributable to the BioReference Transaction, which impacted the amount of amortizable intangible assets.

*Gain on sale of assets.* Gain on sale of assets for the nine months ended September 30, 2024, was \$121.5 million due to the BioReference Transaction that closed during the third quarter of 2024.

**Pharmaceuticals**

(In thousands)	For the nine months ended September 30,			
	2024	2023	Change	% Change
<b>Revenues:</b>				
Revenue from products	\$ 117,675	\$ 124,553	\$ (6,878)	(6)%
Revenue from transfer of intellectual property and other	34,272	165,938	(131,666)	(79)%
Total revenues	151,947	290,491	(138,544)	(48)%
<b>Costs and expenses:</b>				
Cost of revenue	69,856	74,708	(4,852)	(6)%
Selling, general and administrative	44,264	41,895	2,369	6%
Research and development	73,177	68,304	4,873	7%
Contingent consideration	—	(1,023)	1,023	100%
Amortization of intangible assets	49,347	49,397	(50)	(0)%
Total costs and expenses	236,644	233,281	3,363	1%
(Loss) income from operations	\$ (84,697)	\$ 57,210	\$ (141,907)	(248)%

*Revenue from products.* Revenue from products for nine months ended September 30, 2024 decreased \$6.9 million or 5.5%, compared to the nine months ended September 30, 2023. While we experienced higher sales volumes in 2024 compared to 2023, this increase was more than offset by unfavorable foreign exchange fluctuations of approximately \$6.7 million from our international operations, resulting in an overall decrease in revenue. Additionally, revenue from sales of *Royaldee* for the nine months ended September 30, 2024, was \$19.9 million compared to \$21.7 million recorded in the same period in 2023.

*Revenue from transfer of intellectual property and other.* For the nine months ended September 30, 2024, revenue from the transfer of intellectual property and other was \$34.3 million compared to \$165.9 million for the prior period. This decrease was primarily due to one-time milestone payments received in 2023, including a \$90.0 million payment triggered by the FDA approval of NGENLA (Somatrogon), a \$50.0 million payment from Merck for rights granted under the Merck Agreement (as defined and described in Note 14 to our Quarterly Financials), a \$7.0 million payment from VFMCRP triggered by the German price approval for *Royaldee* (as described in Note 14 to our Quarterly Financials) 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 pursuant to the Nicoya Agreement (as described in Note 14 to our Quarterly Financials). For the nine months ended September 30, 2024, revenue from the transfer of intellectual property and other reflects \$18.9 million in gross profit share and royalty payments for NGENLA (Somatrogon) and Pfizer's Genotropin® (Somatotropin), compared with \$11.8 million received in the same period in 2023. Furthermore, revenue for the nine months ended September 30, 2024 included \$12.8 million from the BARDA Contract (as defined and described in Note 14 to our Quarterly Financials).

*Cost of revenue.* Cost of revenue for the nine months ended September 30, 2024 decreased \$4.9 million, a decrease of 6.5% compared to the nine months ended September 30, 2023 which was primarily driven by favorable foreign exchange fluctuations. Despite increased sales volumes during the period, which typically increases cost of revenue, we were able to achieve this decrease due to a combination of factors. Favorable foreign currency fluctuations positively impacted cost of revenue, and we also realized a \$2.6 million reduction in *Royaldee* cost of revenue resulting from a lower standard cost per bottle.

*Selling, general and administrative expenses.* Selling, general and administrative expenses for the nine months ended September 30, 2024 and 2023 were \$44.3 million and \$41.9 million, respectively, an increase of 5.7% from the prior year period. The increase in selling, general and administrative expenses was due to higher employee-related and professional expenses related to our international operations.

*Research and development expenses.* Research and development expenses for the nine months ended September 30, 2024 and 2023 were \$73.2 million and \$68.3 million, respectively, an increase of 7.1% 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 (In thousands)	Nine months ended September 30,	
	2024	2023
External expenses:		
Manufacturing expense for biological products	\$ 22,590	\$ 10,039
Phase III studies	1,332	3,871
Post-marketing studies	514	342
Earlier-stage programs	25,505	37,197
Research and development employee-related expenses	28,132	25,584
Other internal research and development expenses	5,969	3,037
Third-party grants and funding from collaboration agreements	(10,865)	(11,766)
Total research and development expenses	<u>\$ 73,177</u>	<u>\$ 68,304</u>

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Research and development expenses for the nine months ended September 30, 2024, increased primarily to growth in our BARDA collaboration and higher employee-related expenses. These increases were partially offset by a one-time payment to Sanofi of \$12.5 million made in 2023 pursuant to the Sanofi In-License Agreement, which was triggered as a result of the Merck Agreement, and lower costs related to Somatrogen (hGH-CTP) following the closure of open-label extension studies in countries where it has received marketing authorization.

*Contingent consideration.* Contingent consideration for the nine months ended September 30, 2024 was zero, as compared to a \$1.0 million reversal of expense for the nine months ended September 30, 2023. Contingent consideration for the nine months ended September 30, 2023 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 2013.

*Amortization of intangible assets.* Amortization of intangible assets was \$49.4 million for both for the nine months ended September 30, 2024 and 2023. 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. 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,		Change	% Change
	2024	2023		
Costs and expenses:				
Selling, general and administrative	\$ 31,719	\$ 31,789	\$ (70)	(0)%
Research and development	67	52	15	29%
Total costs and expenses	31,786	31,841	(55)	(0)%
Loss from operations	\$ (31,786)	\$ (31,841)	\$ 55	0%

Operating loss for our unallocated corporate operations for the nine months ended September 30, 2024 and 2023 was \$31.8 million and \$31.8 million, respectively, and principally reflect general and administrative expenses incurred in connection with our corporate operations.

### **Other**

*Interest income.* Interest income for the nine months ended September 30, 2024 and 2023 was \$4.1 million and \$3.1 million, respectively. The increase is driven by higher average cash and investment balances as a result of the cash received from the BioReference Transaction and the issuance of the 2044 Notes.

*Interest expense.* Interest expense increased to \$33.2 million for the nine months ended September 30, 2024, compared to \$10.1 million in the same period of 2023. The increase was primarily driven by interest incurred on the 2029 Convertible Notes and the 2044 Senior Secured Notes, including amortization of deferred financing and debt issuance costs. This increase was partially offset by the extinguishment of our outstanding 2023 Convertible Notes in connection with their exchange for 2029 Convertible Notes and the repurchase of a portion of the 2025 Convertible Notes.

*Fair value changes of derivative instruments, net.* Fair value changes of derivative instruments, net for the nine months ended September 30, 2024 and 2023, was \$26.2 million and \$0.8 million of expense, respectively. Derivative expense was principally related to the change in fair value on the 2029 Convertible Notes and on foreign currency forward exchange contracts at OPKO Chile.

*Other income (expense), net.* Other income (expense), net for the nine months ended September 30, 2024, was \$128.8 million of income, compared to \$16.1 million of expense for the 2023 period. Other income (expense), net for the nine months ended September 30, 2024 and 2023, included \$118.6 million of income and \$19.9 million of expense, respectively, as a result of the change in the fair value of our investment in GeneDx Holdings (as defined in Note 6 to our Quarterly Financials). Furthermore, the nine months ended September 30, 2023, reflected \$8.5 million of income due to GeneDx Holdings reaching specific revenue targets for the fiscal year ending December 31, 2022. Finally, a foreign currency gain of \$0.1 million was recorded for the 2024 period, compared with a \$1.8 million loss in the 2023 period.

*Income tax provision.* Our income tax provision for the nine months ended September 30, 2024 and 2023 was a \$21.9 million and \$10.5 million, respectively. For the nine months ended September 30, 2024 and 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, a discrete expense impact related to the BioReference Transaction, the impact of the payments under Merck Agreement, and operating results in tax jurisdictions which do not result in a tax benefit.

*Loss from investments in investees.* We have invested in certain early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as an equityholder. 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 \$7.0 thousand and \$99.0 thousand for the nine months ended September 30, 2024 and 2023, respectively.

## LIQUIDITY AND CAPITAL RESOURCES

On September 30, 2024, we had cash, cash equivalents and restricted cash of approximately \$420.1 million. Cash used in operations of \$139.1 million for the nine months ended September 30, 2024 was primarily driven by a \$121.5 million gain on the sale of assets related to the BioReference Transaction and \$94.6 million change in fair value from equity securities. We also incurred general and administrative expenses related to our corporate operations and research and development activities. Cash from investing activities was \$236.2 million for the nine months ended September 30, 2024 primarily reflected both the proceeds from the BioReference Transaction and the sale of equity securities, offset by capital expenditures. Cash provided by financing activities for the nine months ended September 30, 2024 of \$224.6 million primarily reflected net borrowings on our lines of credit, the issuance of our 2029 Convertible Notes, the issuance of the 2044 Notes, the redemption of the 2025 Notes, and repurchase of shares of our Common Stock. 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 and debt, as well as credit facilities available to us.

In September 2024, ModeX entered into the BARDA Amendment which increased funding by \$26.9 million, for the ongoing 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. The BARDA Amendment also included BARDA's exercise of an option for the development of a multispecific protein antibody for influenza or another pathogen, with the additional funding allocated to cover the expanded work. These modifications increased the total value of the BARDA Contract to \$110.0 million, with a potential value, of \$205.0 million if BARDA exercises all options thereunder to expand MODeX's services. The BARDA Contract covers a five-year period through February 2028. We expect this funding will support the development of a second novel multispecific antibody to SARS-CoV-2, from preclinical through Phase 1 trials, as well as preclinical work on gene-based expression of multispecific antibodies to SARS-CoV-2, including mRNA and/or DNA vectors. In addition, ModeX will begin development of influenza multispecifics with gene and/or protein delivery modalities. As of September 30, 2024, the aggregate amount remaining to be funded by BARDA, which is subject to performance obligations and excluding unexercised contract options, is \$96.0 million.

On September 16, 2024, the Company consummated the BioReference Transaction, pursuant to which Labcorp acquired select assets of the Company's subsidiary, BioReference. Labcorp paid to the Company aggregate consideration of \$237.5 million in cash, subject to certain adjustments as set forth in the Labcorp Asset Purchase Agreement. The assets acquired by Labcorp include BioReference's laboratory testing businesses focused on clinical diagnostics, reproductive health, and women's health across the United States, excluding New York and New Jersey operations.

During the third quarter of 2024, the Company sold 1,386,929 shares of GeneDx Holdings common stock at various prices per share for approximately \$46.7 million in aggregate proceeds. This sale reduced the Company's total ownership in GeneDx Holdings from 13.61% to 8.1% as of September 30, 2024. As of September 30, 2024, the aggregate value of our GeneDx Holdings investment was \$92.2 million based on the closing market price of the GeneDx Holdings common stock.

On July 18, 2024, our Board of Directors authorized the repurchase of up to \$100 million of our Common Stock. Under this program, we may repurchase shares through various methods, including open market purchases, block trades, privately negotiated transactions and accelerated share repurchases, as well as pursuant to pre-set trading plans meeting the requirements of Rule 10b5-1(c) of the Exchange Act, and otherwise in compliance with applicable laws. The timing and volume of repurchases will depend on market conditions, our capital management, investment opportunities, and other factors. The program does not obligate us to repurchase any specific number of shares, has no set expiration date, and may be modified, suspended, or discontinued at our discretion. In connection with this new authorization, the Company repurchased 14,893,026 shares for \$23.8 million during the three months ended September 30, 2024.

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On July 17, 2024, we completed a private offering of \$250 million aggregate principal amount of the 2044 Notes in accordance with the terms of the 2044 Note Purchase Agreement. The 2044 Notes are secured by the Company's profit share payments from Pfizer, received under the Restated Pfizer Agreement. The 2044 Notes bear interest at the 3-month SOFR plus 7.5%, subject to a minimum interest rate of 4.0% per annum. The 2044 Notes mature in July 2044, with interest-only payments required for the first four years.

In January 2024, we completed a private offering of \$230.0 million aggregate principal amount of our 2029 Convertible 144A Notes in accordance with the terms of the 144A Note Purchase Agreement entered into by and between the Company and the Initial Purchaser.

The Company received approximately \$220.0 million of net proceeds from the issuance of the 2029 Convertible 144A Notes, after deducting fees and estimated offering expenses. The Company used approximately \$50.0 million of the net proceeds to repurchase shares of our Common Stock from purchasers of the 2029 Convertible 144A Notes in privately negotiated transactions at a purchase price equal to the closing sale price per share of Common Stock on January 4, 2024, which was \$0.9067. Contemporaneously with the pricing of the 2029 Convertible 144A Notes, the Company entered into separate, privately negotiated transactions with certain holders of the Company's outstanding 4.50% Convertible Senior Notes due 2025 to repurchase, on the closing date, approximately \$144.4 million aggregate principal amount of such notes. The Company effected such repurchases for cash, using \$146.3 million of the net proceeds from the offering of the 2029 Convertible 144A Notes, following which only \$170 thousand aggregate principal amount of the 2025 Notes remained outstanding.

Additionally, the Company issued and sold approximately \$71.1 million aggregate principal amount of the 2029 Convertible Affiliate Notes pursuant to the terms of the Affiliate Note Purchase Agreement by and among the Company and the Affiliate Purchasers. Pursuant to the Affiliate Note Purchase Agreement, the Company issued and sold the 2029 Convertible Affiliate Notes to the Affiliate Purchasers in exchange for \$55.0 million aggregate principal amount of 2023 Convertible Notes, held by the Affiliate Purchasers, together with approximately \$16.1 million of accrued but unpaid interest thereon. Following such exchange, no 2023 Convertible Notes remained outstanding.

Holder may convert their 2029 Convertible Notes at their option prior to the close of business on the business day immediately preceding September 15, 2028 only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ending on March 31, 2024 (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 the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable conversion price on each applicable trading day; (2) during the five consecutive business day period after any ten consecutive trading day period (the "convertible note measurement period") in which the trading price per \$1,000 principal amount of notes for each trading day of the convertible note measurement period was less than 98% of the product of the last reported sale price of our Common Stock and the applicable conversion rate on each such trading day; or (3) upon the occurrence of specified corporate events specified in the indenture governing the 2029 Convertible Notes. On or after September 15, 2028 until the close of business on the business day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing conditions. Upon conversion of a note, 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 conversion rate is initially equal to 869.5652 shares of Common Stock per \$1,000 principal amount of notes (equivalent to an initial conversion price of approximately \$1.15 per share of Common Stock). The conversion rate for the 2029 Convertible Notes is subject to adjustment upon the occurrence of certain events but will not be adjusted for any accrued and unpaid interest.

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.

ModeX and Merck have established a strategic collaboration with a detailed research plan to guide the development of such a vaccine or related product. This plan includes the creation of a joint steering committee and the potential use of third-party contract development and manufacturing organization carry out such activities unless otherwise agreed. Merck will reimburse ModeX for development costs incurred as part of this research plan. To date, we have incurred \$24.5 million of development costs related to the Epstein -Barr Virus, for which Merck has provided reimbursement in full.

As of September 30, 2024, the total commitments under our lines of credit with financial institutions in Chile and Spain were \$30.0 million, of which \$11.7 million was drawn as of September 30, 2024. On September 30, 2024, the weighted average interest rate on these lines of credit was approximately 5.4%. These lines of credit are short-term and are used primarily as a source of working capital. The highest aggregate principal balance at any time outstanding during the nine months ended September 30, 2024 was \$23.6 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.

Separately, on September 16, 2024, BioReference fully repaid its obligations and terminated the Credit Agreement as amended and restated. BioReference paid approximately \$9.7 million to settle its obligations, incurring no prepayment premium or penalty.

In connection with our agreements with Merck, Pfizer, VFMCRP, Nicoya and CAMP4, we are eligible to receive various milestone payments and royalty considerations. Under the terms of the Merck Agreement, we received an initial payment of \$50.0 million and are also eligible to receive up to an additional \$872.5 million upon the achievement of certain commercial and development milestones under several indications. We are also eligible to receive tiered royalty payments ranging from high single digits to low double digits upon achievement of certain sales targets of the Product (as defined in the Merck Agreement). Under the terms of the Restated Pfizer Agreement, we 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 United States 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 VFMCRP Agreement, we are entitled to receive up to an additional \$15 million in regulatory milestones and \$200 million in milestone payments tied to the launch, pricing and sales of *Royaldee*, including a \$7 million regulatory milestone payment we recorded in the first quarter of 2023 triggered by the German price approval for *Royaldee* and \$3 million regulatory milestone payment we recognized in 2022 following the first sale of *Royaldee* 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.

We believe that the cash, cash equivalents and restricted cash on hand at September 30, 2024, which includes the amounts received from the sale of the 2044 Notes and the BioReference Transaction, 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 50 markets, including the United States, Europe, Japan, Australia and Canada, the commercial success of *Royaldee*, 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, existing legal proceedings (including the ITA litigation) and those that may arise in the future. 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.

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The following table provides information as of September 30, 2024, 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,						Total
	2024	2025	2026	2027	2028	Thereafter	
Open purchase orders	\$ 38,588	\$ 4,959	\$ 415	\$ —	\$ —	\$ —	\$ 43,962
Operating leases	3,310	12,382	10,874	10,026	9,245	18,961	64,798
Finance leases	520	1,740	1,316	806	203	1,959	6,544
2029, 2025 and 2033 Convertible Notes	—	170	—	—	—	178,695	178,865
2044 notes	—	—	—	—	—	245,358	245,358
Lines of credit	13,222	—	—	—	—	—	13,222
Interest commitments	2,875	11,387	11,366	11,349	11,363	468	48,808
Total	<u>\$ 58,515</u>	<u>\$ 30,638</u>	<u>\$ 23,971</u>	<u>\$ 22,181</u>	<u>\$ 20,811</u>	<u>\$ 445,441</u>	<u>\$ 601,557</u>

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 Form 10-K that have had a material impact on our Quarterly Financials and related notes.

## RECENT ACCOUNTING PRONOUNCEMENTS

### *Accounting standards yet to be adopted.*

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”), which modifies the rules on income tax disclosures to require entities to disclose (i) specific categories in the rate reconciliation, (ii) the income or loss from continuing operations before income tax expense or benefit (separated between domestic and foreign) and (iii) income tax expense or benefit from continuing operations (separated by federal, state and foreign). ASU 2023-09 also requires entities to disclose their income tax payments to international, federal, state, and local jurisdictions, among other changes. The guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. ASU 2023-09 should be applied on a prospective basis, but retrospective application is permitted. We are currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU No 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (“ASU 2023-07”). ASU 2023-07 enhances disclosures for significant segment expenses for all public entities required to report segment information in accordance with ASC 280. ASC 280 requires a public entity to report for each reportable segment a measure of segment profit or loss that its chief operating decision maker (“CODM”) uses to assess segment performance and to make decisions about resource allocations. The ASU is effective for fiscal years beginning after December 15, 2024 with updates to be applied on a prospective basis with the option to apply the standard retrospectively. Early adoption is permitted. We are currently evaluating the potential impact of adopting this new guidance on our consolidated financial statements and related disclosures.

*Recently adopted accounting standards.*

In 2021, the Organization for Economic Co-operation and Development (“OECD”) established an inclusive framework on base erosion and profit shifting and agreed on a two-pillar solution (“Pillar Two”) to global taxation, focusing on global profit allocation and a 15% global minimum effective tax rate. On December 15, 2022, the EU member states agreed to implement the OECD’s global minimum tax rate of 15%. The OECD issued Pillar Two model rules and continues to release guidance on these rules. The inclusive framework calls for tax law changes by participating countries to take effect in 2024 and 2025. Various countries have enacted or have announced plans to enact new tax laws to implement the global minimum tax. We considered the applicable tax law changes on Pillar Two implementation in the relevant countries, and there is no material impact to our tax results for the period. We anticipate further legislative activity and administrative guidance in 2024, and will continue to evaluate the impacts of enacted legislation and pending legislation to enact Pillar Two Model Rules in the non-US tax jurisdictions we operate in.

**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 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 those for the Chilean Peso and the Euro.

From time to time, we manage our exposure to fluctuations in foreign currency exchange rates through the use of foreign exchange forward contracts. Certain firmly committed transactions may be hedged with foreign exchange forward contracts. As exchange rates fluctuate, 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. We do not enter into foreign exchange or other derivative contracts for trading or speculative purposes.

Our derivative activities, which consist of foreign exchange forward contracts, are intended 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’ respective 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, our results of operations could be negatively impacted due to effectively unhedged 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 22.3% of our revenue for the nine months ended September 30, 2024 was denominated in currencies other than the U.S. Dollar (USD). This compares to 30.7% for the same period in 2023. Our financial statements are reported in USD; therefore, fluctuations in exchange rates affect the translation of foreign-denominated revenue and expenses. In the first nine months of 2024 and for the year ended December 31, 2023, our most significant currency exchange rate exposures were to the Euro and the Chilean Peso. Gross accumulated currency translation adjustments, recorded as a separate component of shareholders' equity, totaled \$36.2 million and 34.6 million at September 30, 2024 and December 31, 2023, respectively. For information on such open foreign exchange forward contracts for the nine months ended September 30, 2024 and 2023 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 subject to minimal interest rate risk due to their very short-term nature. 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 interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income resulting from declining interest rates.

At September 30, 2024, we had cash, cash equivalents and restricted cash of \$420.1 million. The weighted average interest rate related to our cash, cash equivalents and restricted cash for the nine months ended September 30, 2024 was approximately 3.1%. As of September 30, 2024, the principal outstanding balances under our Chilean and Spanish lines of credit was \$11.7 million in the aggregate at a weighted average interest rate of approximately 5.4%.

Our outstanding convertible senior notes have fixed rates of interest; therefore, we are not exposed to interest rate risk on those instruments.

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 management's evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2024.

##### ***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, 2024 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, 2023, or previously reported on Quarterly Reports on Form 10-Q.

**Item 1A. Risk Factors**

There have been no material changes to our risk factors as previously disclosed in our Form 10-K.

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

The following table presents our share repurchase activity for the quarter ended September 30, 2024 [(dollars in thousands, except per share amounts)]

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Dollar Value that May Yet be Purchased Under the Plans or Programs
July 1, 2024 to July 31, 2024	—	\$ -	—	—
August 1, 2024 to August 31, 2024	7,121,936	1.58	7,121,936	92,878,064
September 1, 2024 to September 30, 2024	7,771,090	1.61	7,771,090	85,106,974
Total	14,893,026	\$ 1.60	14,893,026	85,106,974

1. All of the above repurchases were made on the open market at prevailing market rates plus related expenses under our stock repurchase program, which authorizes the repurchase of up to \$100 million of our common stock. We publicly announced this program on July 18, 2024.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not Applicable.

**Item 5. Other Information**

During the quarter ended September 30, 2024, 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**

<a href="#">Exhibit 10.1+</a>	<a href="#">Note Purchase Agreement dated July 17, 2024 by and among the Company, certain purchasers party thereto, OPKO Biologics Limited, Eirgen Pharma Ltd. and HCR Injection SPV, LLC as agent, filed with the Company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2024, and incorporated herein by reference.</a>
<a href="#">Exhibit 10.2</a>	<a href="#">Form of Note, dated July 17, 2024, filed with the Company’s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2024, and incorporated herein by reference.</a>
<a href="#">Exhibit 31.1*</a>	<a href="#">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, 2024.</a>
<a href="#">Exhibit 31.2*</a>	<a href="#">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, 2024.</a>
<a href="#">Exhibit 32.1*</a>	<a href="#">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, 2024.</a>
<a href="#">Exhibit 32.2*</a>	<a href="#">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, 2024.</a>
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)

\* Furnished herewith.

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

**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 7, 2024

**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 7, 2024

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.

Chief Executive Officer

## 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 7, 2024

/s/ Adam Logal

Adam Logal

Senior Vice President and Chief Financial Officer

**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, 2024 (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 7, 2024

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.

Chief Executive Officer

**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, 2024 (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 7, 2024

/s/ Adam Logal

Adam Logal

Senior Vice President and Chief Financial Officer