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, 2021.

OR

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

For the transition period from_____ to _____.

Commission file number 001-33528

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

4400 Biscayne Blvd.
Miami FL 33137

(Address of Principal Executive Offices) (Zip Code)

(305) 575-4100

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ☐ YES ☒ NO

As of October 20, 2021, the registrant had681,341,306 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, including the potential impact of the COVID-19 pandemic on our businesses, operating results, cash flows and/or financial condition. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in "Item 1A-Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020, 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:

- our business may be materially adversely affected by the coronavirus (COVID-19) pandemic, including the impact on our sales and operations from continued or increasing infection rates and potential declines in testing needs should infection rates decline;
- we have had a history of losses and may not generate sustained positive cash flow sufficient to fund our operations and research and development programs;
- our need for, and ability to obtain, additional financing when needed on favorable terms, or at all;
- adverse results in material litigation matters or governmental inquiries;
- the risks inherent in developing, obtaining regulatory approvals for and commercializing new, commercially viable and competitive products and treatments;
- our research and development activities may not result in commercially viable products;
- that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results;
- that we may fail to obtain regulatory approval for hGH-CTP (Somatrogon) or successfully commercialize hGH-CTP (Somatrogon);
- that we may not generate or sustain profits or cash flow from our laboratory operations or substantial revenue from *Rayaldee* and our other pharmaceutical and diagnostic products;
- 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 United States ("U.S.") and other countries, including increasing downward pressure on healthcare reimbursement;
- our ability to manage our growth and our expanded operations;
- increased competition, including price competition;
- changing relationships with payors, including the various state and multi-state programs, suppliers and strategic partners;
- efforts by third-party payors to reduce utilization and reimbursement for clinical testing services;

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

PART I. FINANCIAL INFORMATION

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to the "Company", "OPKO", "we", "our", "ours", and "us" refer to OPKO Health, Inc., a Delaware corporation, including our consolidated subsidiaries.

Item 1. Financial Statements

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

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 148,599	$ 72,211
Accounts receivable, net	255,192	286,314
Inventory, net	112,861	132,341
Other current assets and prepaid expenses	40,858	32,313
Total current assets	557,510	523,179
Property, plant and equipment, net	107,500	140,554
Intangible assets, net	433,855	475,002
In-process research and development	590,200	590,200
Goodwill	674,574	680,602
Investments	11,753	15,731
Operating lease right-of-use assets	33,502	37,735
Other assets	8,744	10,060
Total assets	$ 2,417,638	$ 2,473,063
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 94,393	$ 100,883
Accrued expenses	163,926	240,869
Current maturities of operating leases	9,823	9,028
Current portion of lines of credit and notes payable	14,893	24,703
Total current liabilities	283,035	375,483
Operating lease liabilities	28,256	29,760
Convertible notes	185,543	221,989
Deferred tax liabilities	134,247	137,208
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	20,990	37,072
Total long-term liabilities	369,036	426,029
Total liabilities	652,071	801,512
Equity:		
Common Stock - $0.01 par value, 1,000,000,000 shares authorized; 689,996,658 and 670,585,576 shares issued at September 30, 2021 and December 31, 2020, respectively	6,900	6,706
Treasury Stock - 8,655,082 and 549,907 shares at September 30, 2021 and December 31, 2020, respectively	(1,791)	(1,791)
Additional paid-in capital	3,218,583	3,152,694
Accumulated other comprehensive loss	(19,923)	(4,225)
Accumulated deficit	(1,438,202)	(1,481,833)
Total shareholders' equity	1,765,567	1,671,551
Total liabilities and equity	$ 2,417,638	$ 2,473,063

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

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Revenues:				
Revenue from services	$ 340,163	$ 382,498	$ 1,244,312	$ 804,309
Revenue from products	36,882	28,702	106,490	89,133
Revenue from transfer of intellectual property and other	8,768	16,864	22,585	47,297
Total revenues	385,813	428,064	1,373,387	940,739
Costs and expenses:				
Cost of service revenue	223,193	255,292	830,428	522,973
Cost of product revenue	20,764	17,481	69,943	52,710
Selling, general and administrative	105,120	99,897	330,643	253,749
Research and development	18,306	18,493	55,843	57,862
Contingent consideration	(497)	1,083	(1,556)	1,334
Amortization of intangible assets	12,609	13,879	37,760	43,753
Gain on sale of assets	(31,508)	—	(31,508)	—
Total costs and expenses	347,987	406,125	1,291,553	932,381
Operating income	37,826	21,939	81,834	8,358
Other income and (expense), net:				
Interest income	9	1	21	149
Interest expense	(4,290)	(5,544)	(14,572)	(16,514)
Fair value changes of derivative instruments, net	1,283	(496)	571	112
Other income (expense), net	(3,356)	4,749	(16,067)	10,637
Other income and (expense), net	(6,354)	(1,290)	(30,047)	(5,616)
Income before income taxes and investment losses	31,472	20,649	51,787	2,742
Income tax benefit (provision)	(2,680)	3,178	(7,993)	(4,021)
Net income (loss) before investment losses	28,792	23,827	43,794	(1,279)
Loss from investments in investees	(53)	(110)	(163)	(433)
Net income (loss)	$ 28,739	$ 23,717	$ 43,631	$ (1,712)
Income (loss) per share, basic and diluted:				
Income (loss) per share	$ 0.04	$ 0.04	$ 0.07	$ 0.00
Weighted average common shares outstanding, basic and diluted	651,843,074	640,699,982	646,710,240	640,619,485

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 INCOME (LOSS)
(Unaudited)
(In thousands)

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Net income (loss)	$ 28,739	$ 23,717	$ 43,631	$ (1,712)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss)	(9,991)	8,301	(15,698)	4,619
Comprehensive income	$ 18,748	$ 32,018	$ 27,933	$ 2,907

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, 2021

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at June 30, 2021	689,817,971	$ 6,898	(8,655,082)	$ (1,791)	$ 3,214,351	$ (9,932)	$ (1,466,941)	$ 1,742,585
Equity-based compensation expense	—	—	—	—	3,822	—	—	3,822
Exercise of common stock options and warrants	178,687	2	—	—	410	—	—	412
Net loss	—	—	—	—	—	—	28,739	28,739
Other comprehensive loss	—	—	—	—	—	(9,991)	—	(9,991)
Balance at September 30, 2021	689,996,658	$ 6,900	(8,655,082)	$ (1,791)	$ 3,218,583	$ (19,923)	$ (1,438,202)	$ 1,765,567

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2020	670,585,576	$ 6,706	(549,907)	$ (1,791)	$ 3,152,694	$ (4,225)	$ (1,481,833)	$ 1,671,551
Equity-based compensation expense	—	—	—	—	9,929	—	—	9,929
Exercise of common stock options and warrants	359,812	4	—	—	875	—	—	879
Conversion of 2025 convertible notes	19,051,270	190	(8,105,175)	—	55,085	—	—	55,275
Net income	—	—	—	—	—	—	43,631	43,631
Other comprehensive loss	—	—	—	—	—	(15,698)	—	(15,698)
Balance at September 30, 2021	689,996,658	$ 6,900	(8,655,082)	$ (1,791)	$ 3,218,583	$ (19,923)	$ (1,438,202)	$ 1,765,567

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, 2020

	Common Stock		Treasury					
	Shares	Dollars	Shares	Dollars	Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total
Balance at June 30, 2020	670,378,701	$ 6,704	(549,907)	$ (1,791)	$ 3,147,030	$ (25,752)	$ (1,537,848)	$ 1,588,343
Equity-based compensation expense	—	—	—	—	2,740	—	—	2,740
Exercise of common stock options and warrants	171,500	2	—	—	667	—	—	669
Net income	—	—	—	—	—	—	23,717	23,717
Other comprehensive income	—	—	—	—	—	8,301	—	8,301
Balance at September 30, 2020	670,550,201	$ 6,706	(549,907)	$ (1,791)	$ 3,150,437	$ (17,451)	$ (1,514,131)	$ 1,623,770

	Common Stock		Treasury					
	Shares	Dollars	Shares	Dollars	Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total
Balance at December 31, 2019	670,378,701	$ 6,704	(549,907)	$ (1,791)	$ 3,142,993	$ (22,070)	$ (1,511,077)	$ 1,614,759
Equity-based compensation expense	—	—	—	—	6,777	—	—	6,777
Exercise of common stock options and warrants	171,500	2	—	—	667	—	—	669
Adoption of ASC 326	—	—	—	—	—	—	(1,342)	(1,342)
Net loss	—	—	—	—	—	—	(1,712)	(1,712)
Other comprehensive income	—	—	—	—	—	4,619	—	4,619
Balance at September 30, 2020	670,550,201	$ 6,706	(549,907)	$ (1,791)	$ 3,150,437	$ (17,451)	$ (1,514,131)	$ 1,623,770

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,	
	2021	2020
Cash flows from operating activities:		
Net income (loss)	$ 43,631	$ (1,712)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	59,525	65,295
Non-cash interest	7,164	7,639
Amortization of deferred financing costs	603	626
Losses from investments in investees	163	433
Equity-based compensation – employees and non-employees	9,929	6,777
Non-cash revenue from the transfer of intellectual property	(3,801)	—
Realized loss (gain) on disposal of fixed assets and sales of equity securities	(35,484)	(10,172)
Loss on conversion of the 2025 Notes	11,111	—
Change in fair value of equity securities and derivative instruments	1,919	1,253
Change in fair value of contingent consideration	(1,556)	1,334
Deferred income tax provision	2,378	1,974
Changes in assets and liabilities:		
Accounts receivable, net	27,934	(107,255)
Inventory, net	14,254	(60,565)
Other current assets and prepaid expenses	(13,738)	13,111
Other assets	1,015	(270)
Accounts payable	(4,746)	3,261
Foreign currency measurement	2,382	(782)
Contract liabilities	(13,016)	(4,717)
Accrued expenses and other liabilities	(65,687)	88,988
Net cash provided by operating activities	43,980	5,218
Cash flows from investing activities:		
Proceeds from sale of investments	8,079	15,110
Acquisition of businesses, net of cash	(4,000)	—
Proceeds from the sale of property, plant and equipment	65,975	192
Capital expenditures	(25,426)	(26,885)
Net cash provided by (used in) investing activities	44,628	(11,583)
Cash flows from financing activities:		
Debt issuance costs	(188)	—
Proceeds from the exercise of common stock options and warrants	879	669
Borrowings on lines of credit	1,326,641	699,079
Repayments of lines of credit	(1,338,515)	(742,932)
Net cash used in financing activities	(11,183)	(43,184)
Effect of exchange rate changes on cash and cash equivalents	(1,037)	391
Net increase (decrease) in cash and cash equivalents	76,388	(49,158)
Cash and cash equivalents at beginning of period	72,211	85,452
Cash and cash equivalents at end of period	$ 148,599	$ 36,294
SUPPLEMENTAL INFORMATION:		
Interest paid	$ 8,386	$ 10,657
Income taxes paid, net of refunds	$ 5,509	$ 148
Non-cash financing:		
Shares issued upon the conversion of:		
2025 Convertible Notes	$ 68,775	$ —

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

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

NOTE 1 BUSINESS AND ORGANIZATION

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories, Inc. ("BioReference"), one of the nation's largest full service laboratories with a core genetic testing business and an almost 300-person sales and marketing team to drive growth and leverage new products, including the *4Kscore* test. Our pharmaceutical business features *Rayaldee*, a U.S. Food and Drug Administration ("FDA") approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency and a pipeline of products in various stages of development. Our leading product in development is Somatrogon (hGH-CTP), a once-weekly human growth hormone for which we have partnered with Pfizer, Inc. ("Pfizer") and successfully completed a phase 3 study in August 2019, and for which the FDA has accepted the initial Biologics License Application ("BLA") for filing. We also submitted a New Drug Application (an "NDA") with the Ministry of Health, Labour and Welfare in Japan and a Marketing Authorization Application with the European Medicines Agency. We are incorporated in Delaware, and our principal executive offices are located in leased offices in Miami, Florida.

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

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

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

In June 2021, EirGen Pharma Limited ("EirGen"), our wholly owned subsidiary, entered into a definitive agreement to sellone of its facilities in Waterford, Ireland to Horizon Therapeutics plc for $65 million in cash less certain assumed and accrued liabilities relating to transferred employees. The facility, which was formerly included in our pharmaceutical segment, housed EirGen's sterile-fill-finish business and was no longer a core component of our ongoing operations and business strategy. The transaction closed in the third quarter of 2021. We recognized a gain on the sale of the facility in the third quarter of 2021 of $31.5 million.

NOTE 2 IMPACT OF COVID-19

As the disease caused by SARS-CoV-2, a novel strain of coronavirus, COVID-19 continues to spread and severely impact the U.S. economy and economies of other countries around the world, we continue to be a part of the coordinated public and private sector response to this unprecedented challenge as the COVID-19 pandemic continues. There continues to be a high level of uncertainty relating to how the pandemic will evolve, how governments and consumers will react, progress on the distribution of vaccines and whether the pandemic will have a longer-term effect on the healthcare industry and patient habits. In response to the COVID-19 pandemic, BioReference is providing COVID-19 solutions, including diagnostic molecular testing and serology antibody testing, to meet the testing needs of its numerous customer verticals, including physicians, health systems, long-term care facilities, governments, schools, employers, professional sports teams and entertainment venues, as well as the general public through relationships with retail pharmacy chains.

Revenue from services for the three months ended September 30, 2021 decreased by $42.3 million as compared to 2020 due to a decline in COVID-19 testing volumes. We are unable to predict how long the demand will continue for our COVID-19 related testing, or whether pricing and reimbursement policies for testing will sustain. In addition, overall demand for COVID-19 testing has declined, and accordingly, the sustainability of our COVID-19 testing volumes is uncertain. Additionally, beginning in March 2020, BioReference experienced a decline in testing volumes due to the COVID-19

pandemic; however as stay at home orders and other restrictions have been lifted, we have seen our routine clinical and genomic testing volumes trending towards normalization with prior periods. Should stay at home orders or other restrictions be reenacted, we could see our routine testing levels decline. Excluding COVID-19 test volumes, for the three months ended September 30, 2021, genomic and routine clinical test volume increased 19.1% and 0.7% as compared to volumes for the three months ended September 30, 2020. Additionally, sales of *Rayaldee* have not increased in accordance with its expected growth trajectory as a result of challenges in onboarding new patients due to the COVID-19 pandemic. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, customers closing or severely curtailing their operations (voluntarily or in response to government orders), and the adoption of work-from-home or shelter-in-place policies.

In March 2020, in response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law. The CARES Act provides numerous tax provisions and other stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses, temporary changes to the prior and future limitations on interest deductions, temporary suspension of certain payment requirements for the employer portion of Social Security taxes, technical corrections from prior tax legislation for tax depreciation of certain qualified improvement property, and the creation of certain payroll tax credits associated with the retention of employees.

We have received, or expect to receive a number of benefits under the CARES Act including, but not limited to:

- During the second quarter of 2020, we received approximately $14 million under The Centers for Medicare & Medicaid Services (CMS) Accelerated and Advance Payment Program, which provides accelerated payments to Medicare providers/suppliers working to provide treatment to patients and combat the COVID-19 pandemic, and the amounts advanced are loans which will be offset against future claims and must be repaid in 2021. These loans are initially recorded as contract liabilities included in Accrued expenses and are reduced as the amounts are recouped by CMS;
- We were eligible to defer depositing the employer's share of Social Security taxes for payments due from March 27, 2020 through December 31, 2020, interest-free and penalty-free;
- We received approximately $16.2 million during 2020 from the funds that were distributed to healthcare providers for related expenses or lost revenues that are attributable to the COVID-19 pandemic. We recognized the $16.2 million grant in other revenues for the year ended December 31, 2020;
- U.S. Department of Health and Human Services (HHS), will provide claims reimbursement to healthcare providers generally at Medicare rates for testing uninsured patients; and
- Clinical laboratories are provided a one-year reprieve from the reporting requirements under the Protecting Access to Medicare Act ("PAMA") as well as a one-year delay of reimbursement rate reductions for clinical laboratory services provided under Medicare that were scheduled to take place in 2021.

Since the pandemic began in the U.S., we have invested in testing capabilities and infrastructure to meet demand for our molecular and antibody testing for COVID-19. In 2021, we kicked off company-wide lab operations specimen acquisition, logistics, procurement, customer service, cost reduction initiatives to rightsize our cost structure to match the declining COVID testing volumes and to drive efficiency gains in our core clinical lines of business.

Three vaccines for COVID-19 have received approval or emergency authorization and have had increasingly widespread acceptance. However, we believe that, based on our experience with the pandemic, the high medical need for efficient and widespread testing for COVID-19 will extend beyond the current phase of the pandemic. Our belief is supported by the unprecedented healthcare and economic impact of the pandemic thus far, the uneven and incomplete rollout of vaccines and the fact that significant portions of the U.S. population may never be vaccinated, and the continued likelihood of surges of COVID-19 including from new strains of SARS-CoV-2 with uncertain susceptibility to the current vaccines. We believe that these factors have greatly magnified the need for more effective therapeutics, and the need for efficient and widespread testing, with properties targeted to the disease processes caused by serious viral infections.

NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation. The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") and with the instructions to Form 10-Q and

Article 10 of Regulation S-X. Accordingly, they do not include all information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments or adjustments otherwise disclosed herein) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three and nine months ended September 30, 2021 are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2021 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, 2020.

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

Use of estimates. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from these estimates.

Cash and cash equivalents. Cash and cash equivalents include short-term, interest-bearing instruments with original maturities of 90 days or less at the date of purchase. We also consider all highly liquid investments with original maturities at the date of purchase of 90 days or less as cash equivalents. These investments include money markets, bank deposits, certificates of deposit and U.S. treasury securities.

Inventories. Inventories are valued at the lower of cost and net realizable value. Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost and net realizable value. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which are used in our testing laboratories. Inventory obsolescence expense for the three and nine months ended September 30, 2021 was $1.3 million and $5.3 million, respectively. Inventory obsolescence expense for the three and nine months ended September 30, 2020 was $1.7 million and $3.4 million, respectively.

Pre-launch inventories. We may accumulate commercial quantities of certain product candidates prior to the date we anticipate that such products will receive final FDA approval. The accumulation of such pre-launch inventories exposes us to the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever; however, we may accumulate pre-launch inventories depending on the commercial value of the applicable product launch opportunity. In accordance with our policy, we expense this pre-launch inventory.

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 $1.7 billion at both September 30, 2021 and December 31, 2020.

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.

Goodwill was $674.6 million and $680.6 million, respectively, at September 30, 2021 and December 31, 2020. 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.

Net intangible assets other than goodwill was $1.0 billion and $1.1 billion, including IPR&D of $590.2 million, at September 30, 2021 and December 31, 2020, respectively. Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products and IPR&D. Considering the high risk nature of research and

development and the industry's success rate of bringing developmental compounds to market, IPR&D impairment charges may occur in future periods. Estimating the fair value of IPR&D for potential impairment is highly sensitive to changes in projections and assumptions and changes in assumptions could potentially lead to impairment.

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

We believe that our estimates and assumptions are reasonable and otherwise consistent with assumptions that marketplace participants would use in their estimates of fair value. However, if future results are not consistent with our estimates and assumptions, including as a result of the COVID-19 global pandemic, then we may be exposed to an impairment charge, which could be material.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from3 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 $37.8 million and $43.8 million for the nine months ended September 30, 2021 and 2020, respectively.

Fair value measurements. The carrying amounts of our cash and cash equivalents, accounts receivable, accounts payable and short-term debt approximate their fair value due to the short-term maturities of these instruments. Investments that are considered equity securities as of September 30, 2021 and December 31, 2020 are predominately carried at fair value. Our debt under the credit agreement with JPMorgan Chase Bank, N.A. approximates fair value due to the variable rate of interest applicable to such debt.

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

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

Derivative financial instruments. We record derivative financial instruments on our Condensed Consolidated Balance Sheet at their fair value and recognize the changes in the fair value in our Condensed Consolidated Statement of Operations when they occur, the only exception being derivatives that qualify as hedges. For the derivative instrument to qualify as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2021 and December 31, 2020, our foreign currency forward contracts held to economically hedge inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognized all changes in the fair values of our derivatives instruments, net, in our Condensed Consolidated Statement of Operations. Refer to Note 10.

Property, plant and equipment. Property, plant and equipment are recorded at cost or fair value if acquired in a business combination. Depreciation is provided using the straight-line method over the estimated useful lives of the assets and includes amortization expense for assets capitalized under finance leases. The estimated useful lives by asset class are as follows: software - 3 years, machinery, medical and other equipment - 5-8 years, furniture and fixtures - 5-12 years, leasehold improvements - the lesser of their useful life or the lease term, buildings and improvements - 10-40 years, and automobiles - 3-5 years. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation expense was $6.4 million and $21.8 million for the three and nine months ended September 30, 2021, respectively. Depreciation expense was $7.2 million and $21.5 million for the three and nine months ended September 30, 2020, respectively. Assets held under finance leases are included within Property, plant and equipment, net in our Condensed Consolidated Balance Sheet and are amortized

over the shorter of their useful lives or the expected term of their related leases. Assets to be disposed of by sale are recognized as held for sale at the lower of carrying value or fair value less costs to sell.

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

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

We operate in various countries and tax jurisdictions globally. For interim reporting purposes, we record income taxes based on the expected effective income tax rate, taking into consideration year to date and global forecasted tax results. For the three and nine months ended September 30, 2021, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the valuation allowance against certain U.S. and non-U.S. deferred tax assets, the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, and the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

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

We apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we review the contract to determine which performance obligations we must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. 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, we do not believe that such receivables represent a credit risk because the related healthcare programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. At September 30, 2021 and December 31, 2020, receivable balances (net of explicit and implicit price concessions) from Medicare and Medicaid were 7% and 6%, respectively, of our consolidated Accounts receivable, net. At September 30, 2021 and December 31, 2020, receivable balances (net of explicit and implicit price concessions) due directly from states, cities and other municipalities, specifically related to our real-time reverse-transcription polymerase chain reaction (real-time RT-PCR) assay to detect COVID-19, were 1.6% and 6.3% of our consolidated accounts receivable, net, respectively.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At September 30, 2021 and December 31, 2020, receivables due from patients represented approximately 1.5% and 0.7%, 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 $2.3 million and $2.1 million at September 30, 2021 and December 31, 2020, respectively. The credit loss expense for the three and nine months ended September 30, 2021 was $0.0 million and $0.6 million, respectively. The credit loss expense for the three and nine months ended September 30, 2020 was $0.1 million and $0.3 million, respectively.

Equity-based compensation. We measure the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits realized from the exercise of stock options as cash flows from operations. For the three and nine months ended September 30, 2021 we recorded $3.8 million and $9.9 million, respectively, of equity-based compensation expense. For the three and nine months ended September 30, 2020, we recorded $2.7 million and $6.8 million, respectively, of equity-based compensation expense.

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

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

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

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

Foreign currency translation. The financial statements of certain of our foreign operations are measured using the local currency as the functional currency. The local currency assets and liabilities are generally translated at the rate of exchange to the U.S. dollar on the balance sheet date and 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).

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.

Pending accounting pronouncements.

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)." ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. The ASU is effective for public entities for fiscal years beginning after December 15, 2021, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

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 par value $0.01 per share ("Common Stock") outstanding during the period. Shares of Common Stock outstanding under the share lending arrangement entered into in conjunction with the 2025 Notes (as defined in Note 7) are excluded from the calculation of basic and diluted earnings per share because the borrower of the shares is required under the share lending arrangement to refund any dividends paid on the shares lent. Refer to Note 7. For diluted earnings per share, the dilutive impact of stock options and warrants is determined by applying the "treasury stock" method. The dilutive impact of the 2033 Senior Notes, the 2023 Convertible Notes and the 2025 Notes (each, as defined and discussed in Note 7) has been considered using the "if converted" method. For periods in which their effect would be antidilutive, no effect is given to Common Stock issuable under outstanding options or warrants or the potentially dilutive shares issuable pursuant to the 2033 Senior Notes, the 2023 Convertible Notes and the 2025 Notes in the dilutive computation.

A total of 57,508,233 and 73,412,800 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the three months ended September 30, 2021, and 2020, respectively, because their inclusion would be antidilutive. A total of 64,515,129 and 69,661,016 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2021, and 2020, respectively, because their inclusion would be antidilutive. A full presentation of diluted earnings per share has not been provided because the required adjustments to the numerator and denominator resulted in diluted earnings per share equivalent to basic earnings per share.

During the three months ended September 30, 2021, 178,687 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 178,687 shares of Common Stock. Of the 178,687 Common Stock options and Common Stock warrants exercised, no shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the nine months ended September 30, 2021, 358,812 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 358,812 shares of Common Stock. Of the 358,812 Common Stock options and Common Stock warrants exercised, no shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the three and nine months ended September 30, 2020, 171,500 Common Stock options or Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 171,500 shares of Common Stock. Of the 171,500 Common Stock options and Common Stock warrants exercised, no shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

NOTE 5 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	September 30, 2021	December 31, 2020
Accounts receivable, net:		
Accounts receivable	$ 257,512	$ 288,369
Less: allowance for credit losses	(2,320)	(2,055)
	$ 255,192	$ 286,314
Inventories, net:		
Consumable supplies	$ 67,978	$ 86,779
Finished products	40,642	36,831
Work in-process	2,768	5,268
Raw materials	6,161	5,784
Less: inventory reserve	(4,688)	(2,321)
	$ 112,861	$ 132,341
Other current assets and prepaid expenses:		
Taxes recoverable	$ 9,680	$ 13,440
Prepaid expenses	11,890	7,259
Prepaid insurance	7,630	3,803
Other receivables	655	2,502
Other	11,003	5,309
	$ 40,858	$ 32,313
Intangible assets, net:		
Customer relationships	$ 450,292	$ 448,751
Technologies	286,059	296,623
Trade names	49,783	49,820
Covenants not to compete	16,324	16,334
Licenses	5,766	5,766
Product registrations	7,261	8,025
Other	6,231	6,513
Less: accumulated amortization	(387,861)	(356,830)
	$ 433,855	$ 475,002
Accrued expenses:		
Inventory received but not invoiced	$ 30,053	$ 72,160
Commitments and contingencies	20,141	15,454
Employee benefits	43,242	43,300
Contract liabilities	3,004	15,783
Clinical trials	4,993	7,112
Contingent consideration	487	1,188
Finance leases short-term	1,809	2,453
Professional fees	4,889	4,985
Other	55,308	78,434
	$ 163,926	$ 240,869

(In thousands)	September 30, 2021	December 31, 2020
Other long-term liabilities:		
Contingent consideration	$ 2,498	$ 4,507
Mortgages and other debts payable	1,671	3,837
Finance leases long-term	2,302	2,805
Contract liabilities	357	595
Other	14,162	25,328
	$ 20,990	$ 37,072

Our intangible assets and goodwill relate principally to our completed acquisitions of OPKO Renal, OPKO Biologics, EirGen and BioReference. 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 - 7-20 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.

The changes in value of the intangible assets and goodwill during the nine months ended September 30, 2021 were primarily due to foreign currency fluctuations between the Chilean Peso, and the Euro against the U.S. dollar.

The following table summarizes the changes in Goodwill by reporting unit during the nine months ended September 30, 2021.

	2021				
(In thousands)	Gross goodwill at January 1	Cumulative impairment at January 1	Goodwill impairment	Foreign exchange and other	Balance at September 30
Pharmaceuticals					
CURNA	$ 4,827	$ (4,827)	$ —	$ —	$ —
Rayaldee	93,418	—	—	(5,028)	88,390
FineTech	11,698	(11,698)	—	—	—
OPKO Biologics	139,784	—	—	—	139,784
OPKO Chile	4,505	—	—	(556)	3,949
OPKO Health Europe	8,086	—	—	(444)	7,642
OPKO Mexico	100	(100)	—	—	—
Transition Therapeutics	3,421	(3,421)	—	—	—
Diagnostics					
BioReference	434,809	—	—	—	434,809
OPKO Diagnostics	17,977	(17,977)	—	—	—
	$ 718,625	$ (38,023)	$ —	$ (6,028)	$ 674,574

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, 2021 and December 31, 2020:

(in thousands)	As of September 30, 2021		As of December 31, 2020	
Investment type	Investment Carrying Value	Underlying Equity in Net Assets	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	$ 727	$ 9,055	$ 426	$ 2,252
Variable interest entity, equity method	1,023	—	1,060	9
Equity securities	6,548		14,136	
Equity securities with no readily determinable fair value	3,409		35	
Warrants and options	46		74	
Total carrying value of investments	$ 11,753		$ 15,731	

Equity method investments

Our equity method investments consist of investments in Pharmsynthez (ownership9%), Cocrystal Pharma, Inc. (“COCP”) (3%), Non-Invasive Monitoring Systems, Inc. (“NIMS”) (1%), Neovasc, Inc. (“Neovasc”) (1%), InCellDx, Inc. (“InCellDx”) (29%), BioCardia, Inc. (“BioCardia”) (1%), Xenetic Biosciences, Inc. (“Xenetic”) (2%), and LeaderMed Health Group Limited (“LeaderMed”) (47%). The aggregate amount of assets, liabilities, and net losses of our equity method investees as of and for the nine months ended September 30, 2021 were $236.7 million, $42.1 million, and $49.0 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, 2020 were $90.9 million, $28.4 million, and $75.4 million, respectively. We have determined that we and/or our related parties can significantly influence control of our equity method investments through our board representation and/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 Condensed 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, 2021 was $6.3 million.

Investments in Equity Securities

Our equity securities consist of investments in Phio Pharmaceuticals (“Phio”) (ownership0.01%), VBI Vaccines Inc. (“VBI”) (1%), ChromaDex Corporation (“ChromaDex”) (0.1%), Eloxx Pharmaceuticals, Inc. (“Eloxx”) (2%), and CAMP4 Therapeutics Corporation (“CAMP4”) (9%). We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of these investments. Accordingly, we account for our investment in these entities as equity securities, and we record changes in the fair value of these investments in Other income (expense) each reporting period when they have readily determinable fair value. Equity securities without a readily determinable fair value are adjusted to fair value when there is an observable price change. Net gains and losses on our equity securities for the nine months ended September 30, 2021, and 2020 were as follows:

	For the nine months ended September 30	
(in thousands)	2021	2020
Equity Securities:		
Net gains and losses recognized during the period on equity securities	$ 491	$ 8,959
Less: Net gains and losses realized during the period on equity securities	(2,981)	10,324
Unrealized net gains and losses recognized during the period on equity securities still held at the reporting date	$ (2,490)	$ (1,365)

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, 2021 and December 31, 2020, and 33 thousand, 0.7 million, 40 thousand and 404 warrants to purchase shares of COCP, InCellDx, Inc., Xenetic, and Phio, respectively. We recorded the changes in the fair value of the options and warrants in Fair value changes of derivative instruments, net in our Condensed Consolidated Statement of Operations. We also recorded the fair value of the options and warrants in Investments, net in our Condensed Consolidated Balance Sheet. See further discussion of the Company's options and warrants in Note 9 and Note 10.

Investments in variable interest entities

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

In August 2020, GeneDx, Inc., a subsidiary of BioReference, announced that it had entered into an agreement with Pediatrix Medical Group ("Pediatrix"), a provider of maternal-fetal, and pediatric medical and surgical subspecialty physician services, to offer genomic sequencing to support clinical diagnosis in neonatal intensive care units staffed by Pediatrix's affiliated neonatologists. The offering is planned to include whole exome and whole genome sequencing and genomic support services under the brand Detect Genomix.

Our initial capital investment in Detect Genomix was $245,000 for which we received a 49% ownership interest in Detect Genomix. We are required to make additional capital contributions to Detect Genomix in accordance with our percentage interests if Detect Genomix is unable to generate positive cash flow from operations or is unable to obtain alternative financing. We have not made any other investments in or loans to Detect Genomix through September 30, 2021.

In order to determine the primary beneficiary of Detect Genomix, we evaluated our investment to identify if we had the power to direct the activities that most significantly impact the economic performance of Detect Genomix. Based on the capital structure, governing documents and overall business operations of Detect Genomix, we determined that, while a VIE, we do not have the power to direct the activities that most significantly impact Detect Genomix's economic performance. We determined, however, that we can significantly influence control of Detect Genomix through our board representation and voting power. Therefore, we have the ability to exercise significant influence over Detect Genomix's operations and account for our investment in Detect Genomix under the equity method.

We own 1,260,000 shares of Zebra Series A-2 Preferred Stock and 900,000 shares of Zebra restricted common stock (ownership 29% at September 30, 2021). 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 member of our Board of Directors, is a founder of Zebra and, along with Dr. Frost, serves as a member of Zebra's Board of Directors.

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

NOTE 7 DEBT

As of September 30, 2021 and December 31, 2020, our debt consisted of the following:

(In thousands)	September 30, 2021	December 31, 2020
2025 Notes	$ 117,661	$ 156,163
2023 Convertible Notes	64,832	62,776
2033 Senior Notes	3,050	3,050
JP Morgan Chase	—	7,057
Chilean and Spanish lines of credit	14,064	15,897
Current portion of notes payable	829	1,749
Long term portion of notes payable	2,151	4,513
Total	$ 202,587	$ 251,205
Balance sheet captions		
Convertible Notes	$ 185,543	$ 221,989
Current portion of lines of credit and notes payable	14,893	24,703
LT notes payable included in long-term liabilities	2,151	4,513
Total	$ 202,587	$ 251,205

On February 25, 2020, we entered into a credit agreement with an affiliate of Dr. Frost, pursuant to which the lender committed to provide us with an unsecured line of credit in the amount of $100 million. The line of credit called for a commitment fee equal to 0.25% per annum of the unused portion of the line. We terminated this line of credit in June 2021 and as of September 30, 2021, no amount was outstanding thereunder.

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 notes mature on February 15, 2025, unless earlier repurchased, redeemed or converted.

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

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

We may not redeem the 2025 Notes prior to February 15, 2022. We may redeem for cash any or all of the 2025 Notes, at our option, on or after February 15, 2022, if the last reported sale price of our Common Stock has been at least 130% of the then

current conversion price for the notes for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide a notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2025 Notes.

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

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

In conjunction with the issuance of the 2025 Notes, we agreed to loan up to 30,000,000 shares of our Common Stock to affiliates of the underwriter in order to assist investors in the 2025 Notes to hedge their position. Following consummation of the Exchange, the number of outstanding borrowed shares of Common Stock was reduced by approximately 8,105,175 shares. As of September 30, 2021 and December 31, 2020, a total of 21,144,825 and 29,250,000 shares remained outstanding under the share lending arrangement, respectively. We will not receive any of the proceeds from the sale of the borrowed shares, but we received a one-time nominal fee of $0.3 million for the newly issued shares. Shares of our Common Stock outstanding under the share lending arrangement are excluded from the calculation of basic and diluted earnings per share. See Note 4.

As required by ASC 470-20, "Debt with Conversion and Other Options," we calculated the equity component of the 2025 Notes, taking into account both the fair value of the conversion option and the fair value of the share lending arrangement. The equity component was valued at $52.6 million at issue date and this amount was recorded as Additional paid-in capital, which resulted in a discount on the 2025 Notes. The discount is being amortized to Interest expense over the term of the 2025 Notes, which results in an effective interest rate on the 2025 Notes of 11.2%.

The following table sets forth information related to the 2025 Notes which is included in our Condensed Consolidated Balance Sheet as of September 30, 2021:

(In thousands)	2025 Senior Notes	Discount	Debt Issuance Cost	Total
Balance at December 31, 2020	$ 200,000	$ (39,537)	$ (4,300)	$ 156,163
Amortization of debt discount and debt issuance costs	—	5,107	556	5,663
Conversion	(55,420)	10,151	1,104	(44,165)
Balance at September 30, 2021	$ 144,580	$ (24,279)	$ (2,640)	$ 117,661

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 2023 Convertible Notes mature five years following the date of issuance. Each holder of a 2023 Convertible Note has the option, from time to time, to convert all or any portion of the outstanding principal balance of such 2023 Convertible Note, together with accrued and unpaid interest thereon, into shares of our Common Stock at a conversion price of $5.00 per share. We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon, pro rata among the holders, upon no fewer than 30 days, and no more than 60 days, notice to the holders. The 2023 Convertible Notes contain customary events of default and representations and warranties of OPKO.

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

In January 2013, we entered into note purchase agreements with respect to the issuance and sale of our 3.0% Senior Notes due 2033 (the "2033 Senior Notes") in a private placement exempt from registration under the Securities Act. We issued the 2033 Senior Notes on January 30, 2013. The 2033 Senior Notes, which totaled $175.0 million in original principal amount,

bear interest at the rate of3.0% per year, payable semiannually on February 1 and August 1 of each year. The 2033 Senior Notes mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change, as defined in the indenture governing the 2033 Senior Notes, subject to certain exceptions, the holders may require us to repurchase all or any portion of their 2033 Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the 2033 Senior Notes being repurchased, plus any accrued and unpaid interest to, but not including, the related fundamental change repurchase date.

From 2013 to 2016, holders of the 2033 Senior Notes converted $143.2 million in aggregate principal amount into an aggregate of21,539,873 shares of Common Stock. On February 1, 2019, approximately $28.8 million aggregate principal amount of 2033 Senior Notes were tendered by holders pursuant to such holders' option to require us to repurchase the 2033 Senior Notes as set forth in the indenture, governing the 2033 Senior Notes, following which repurchase only $3.0 million aggregate principal amount of the 2033 Senior Notes remained outstanding. Holders of the remaining $3.0 million principal amount of the 2033 Senior Notes may require us to repurchase such notes for100% of their principal amount, plus accrued and unpaid interest, on February 1, 2023, on February 1, 2028, or following the occurrence of a fundamental change as described above.

The terms of the 2033 Senior Notes, include, among others: (i) rights to convert the notes into shares of our Common Stock, including upon a fundamental change; and (ii) a coupon make-whole payment in the event of a conversion by the holders of the 2033 Senior Notes on or after February 1, 2017 but prior to February 1, 2019. We determined that these specific terms were embedded derivatives. Embedded derivatives are required to be separated from the host contract, the 2033 Senior Notes, and carried at fair value when: (a) the embedded derivative possesses economic characteristics that are not clearly and closely related to the economic characteristics of the host contract; and (b) a separate, stand-alone instrument with the same terms would qualify as a derivative instrument. We concluded that the embedded derivatives within the 2033 Senior Notes met these criteria and, as such, were valued separate and apart from the 2033 Senior Notes and recorded at fair value each reporting period.

For accounting and financial reporting purposes, we combined these embedded derivatives and valued them together as one unit of accounting. In 2017, certain terms of the embedded derivatives expired pursuant to the original agreement and the embedded derivatives no longer met the criteria to be separated from the host contract and, as a result, the embedded derivatives were no longer required to be valued separate and apart from the 2033 Senior Notes and were reclassified to additional paid in capital.

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

On August 30, 2021, the Credit Agreement was amended and restated (the "A&R Credit Agreement"). The A&R Credit Agreement is guaranteed by all of BioReference's domestic subsidiaries. The A&R Credit Agreement is also secured by substantially all assets of BioReference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in BioReference. Availability under the A&R Credit Agreement is based on a borrowing base composed of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein. As of September 30, 2021, $64.3 million remained available for borrowing under the Credit Agreement. Principal under the Credit Agreement is due upon maturity on August 30, 2024.

At BioReference's option, borrowings under the A&R Credit Agreement (other than swingline loans) will bear interest at (i) the CB floating rate (defined as the higher of (a) the prime rate and (b) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) for an interest period of one month plus 2.50%) plus an applicable margin of 0.75% or (ii) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) plus an applicable margin of1.75%. Swingline loans will bear interest at the CB floating rate plus the applicable margin. The A&R Credit Agreement also calls for other customary fees and charges, including an unused commitment fee of 0.375% if the average quarterly availability is 50% or more of the revolving commitment, or0.25% if the average quarterly availability is less than or equal to 50% of the revolving commitments.

As of September 30, 2021 and December 31, 2020,no amount and $7.1 million, respectively, was outstanding under the A&R Credit Agreement.

The A&R Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require BioReference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws and restrictions on the ability of BioReference and its

subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the A&R Credit Agreement, notwithstanding the ability of BioReference to meet its debt service obligations. The A&R Credit Agreement also includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the A&R Credit Agreement and execution upon the collateral securing obligations under the A&R Credit Agreement. Substantially all the assets of BioReference and its subsidiaries are restricted from sale, transfer, lease, disposal or distributions to the Company, subject to certain exceptions. As of September 30, 2021, BioReference and its subsidiaries had net assets of approximately $1,119.0 million, which included goodwill of $434.8 million and intangible assets of $310.7 million.

In addition to the A&R Credit Agreement with CB, we had line of credit agreements witheleven other financial institutions as of both September 30, 2021 and December 31, 2020 in the U.S., Chile and Spain. These lines of credit are used primarily as sources of working capital for inventory purchases.

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

(Dollars in thousands)			Balance Outstanding	
Lender	Interest rate on borrowings at September 30, 2021	Credit line capacity	September 30, 2021	December 31, 2020
JPMorgan Chase	3.25%	$ 75,000	$ —	$ 7,057
Itau Bank	5.50%	2,128	2,128	2,353
Bank of Chile	6.60%	2,275	772	1,494
BICE Bank	5.50%	2,500	1,534	1,166
Scotiabank	5.50%	4,500	2	1,829
Santander Bank	5.50%	4,500	836	3,025
Security Bank	5.50%	1,937	1,937	262
Estado Bank	5.50%	4,700	2,111	2,127
BCI Bank	5.00%	2,500	2,171	—
Corpbanca	5.00%	2,573	2,573	3,641
Banco De Sabadell	1.75%	579	—	—
Santander Bank	1.82%	579	—	—
Total		$ 103,771	$ 14,064	$ 22,954

At September 30, 2021 and December 31, 2020, the weighted average interest rate on our lines of credit was approximately5.4% and 4.9%, respectively.

At September 30, 2021 and December 31, 2020, we had notes payable and other debt (excluding the 2033 Senior Notes, the 2023 Convertible Notes, the 2025 Notes, the A&R Credit Agreement and amounts outstanding under lines of credit described above) as follows:

(In thousands)	September 30, 2021	December 31, 2020
Current portion of notes payable	$ 829	$ 1,749
Other long-term liabilities	2,151	4,513
Total	$ 2,980	$ 6,262

The notes and other debt mature at various dates ranging from 2020 through 2024, bearing variable interest rates from0.7% up to 3.8%. The weighted average interest rate on the notes and other debt was 1.7% and 2.9% on September 30, 2021 and December 31, 2020. The notes are partially secured by our office space in Barcelona.

NOTE 8 ACCUMULATED OTHER COMPREHENSIVE LOSS

For the nine months ended September 30, 2021, changes in Accumulated other comprehensive loss, net of tax, were as follows:

(In thousands)	Foreign currency translation
Balance at December 31, 2020	$ (4,225)
Other comprehensive loss	(15,698)
Balance at September 30, 2021	$ (19,923)

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, 2021, we had equity securities (refer to Note 6), forward foreign currency exchange contracts for inventory purchases (refer to Note 10) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics and OPKO Renal that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with BioCardia, we record the related BioCardia options at fair value as well as the warrants from COCP, InCellDx, Xenetic and Phio.

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

	Fair value measurements as of September 30, 2021			
(In thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Equity securities	$ 6,548	$ —	$ —	$ 6,548
Common stock options/warrants	—	46	—	46
Forward contracts	—	684	—	684
Total assets	$ 6,548	$ 730	$ —	$ 7,278
Liabilities:				
Contingent consideration	—	—	2,985	2,985
Total liabilities	$ —	$ —	$ 2,985	$ 2,985

	Fair value measurements as of December 31, 2020			
(In thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Equity securities	$ 14,136	$ —	$ —	$ 14,136
Common stock options/warrants	—	74	—	74
Total assets	$ 14,136	$ 74	$ —	$ 14,210
Liabilities:				
Forward contracts	—	1,040	—	1,040
Contingent consideration	—	—	5,695	5,695
Total liabilities	$ —	$ 1,040	$ 5,695	$ 6,735

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

	September 30, 2021				
(In thousands)	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2025 Notes	$ 117,661	$ 179,046	$ —	$ 179,046	$ —

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

As of September 30, 2021 and December 31, 2020, the carrying value of our other financial instrument assets approximates their fair value due to their short-term nature or variable rate of interest.

The following table reconciles the beginning and ending balances of our Level 3 assets and liabilities as of September 30, 2021:

	September 30, 2021
(In thousands)	Contingent consideration
Balance at December 31, 2020	$ 5,695
Change in fair value:	
Included in results of operations	(1,556)
Foreign currency impact	8
Payments	(1,162)
Balance at September 30, 2021	$ 2,985

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

Contingent consideration – We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to OPKO Diagnostics, CURNA and OPKO Renal transactions. As of September 30, 2021, of the $3.0 million of contingent consideration, $0.5 million was recorded in Accrued expenses and $2.5 million was recorded in Other long-term liabilities. As of December 31, 2020, of the $5.7 million of contingent consideration, $1.2 million was recorded in Accrued expenses and $4.5 million was recorded in Other long-term liabilities. As a result of our execution of the CAMP4 Agreement (as defined in Note 14), we will have to pay a percentage of any payments received under the CAMP4 Agreement to the former CURNA stockholders.

NOTE 10 DERIVATIVE CONTRACTS

The following table summarizes the fair values and the presentation of our derivative assets (liabilities) in the Condensed Consolidated Balance Sheets:

(In thousands)	Balance Sheet Component	September 30, 2021	December 31, 2020
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 46	$ 74
Forward contracts	Unrealized gains on forward contracts are recorded in Other current assets and prepaid expenses. Unrealized (losses) on forward contracts are recorded in Accrued expenses.	$ 684	$ (1,040)

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, 2021 and December 31, 2020, 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, 2021 and 2020:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	2021	2020	2021	2020
Derivative gain (loss):				
Common Stock options/warrants	$ (22)	$ (13)	$ (28)	$ (82)
Forward contracts	1,305	(483)	599	194
Total	$ 1,283	$ (496)	$ 571	$ 112

NOTE 11 RELATED PARTY TRANSACTIONS

In August 2020, we paid a $125,000 filing fee to the Federal Trade Commission (the "FTC") in connection with filings made by us and Dr. Jane Hsiao, our Vice Chairman and Chief Technical Officer, under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR Act") relating to her percentage equity ownership interest in OPKO and potential future purchases of our Common Stock.

In August 2020, Dr. Phillip Frost, our Chairman and Chief Executive Officer, paid a filing fee of $280,000 to the FTC under the HSR Act in connection with filings made by us and Dr. Frost, relating to his percentage equity ownership interest in OPKO and potential future purchases of our Common Stock. We reimbursed Dr. Frost for the HSR filing fee.

In August 2020, GeneDx, Inc., a subsidiary of BioReference, entered into an agreement with Mednax Services, Inc. ("Mednax Services"), a subsidiary of MEDNAX, Inc., ("MEDNAX") pursuant to which the parties formed a joint venture under the brand Detect Genomix. GeneDx's initial capital investment in Detect Genomix was $245,000 for which GeneDx received a 49% ownership interest in Detect Genomix, and Mednax Services contributed $255,000 in exchange for a 51% ownership interest in Detect Genomix. Adam Logal, the Company's CFO, is the chair and sits on the Board of Managers of the joint venture. Mednax Services provides administrative services to the joint venture pursuant to an administrative services agreement. GeneDx provides laboratory services to the joint venture. Dr. Roger Medel, a director of the Company, is the former Chief Executive Officer of MEDNAX and Mednax Services. Dr. Medel serves on the board of MEDNAX.

On February 25, 2020, we entered into a credit agreement with an affiliate of Dr. Frost, pursuant to which the lender committed to provide us with an unsecured line of credit in the amount of $100 million. The line of credit called for a commitment fee equal to 0.25% per annum of the unused portion of the line. We terminated this line of credit in June 2021 and as of September 30, 2021, no amount was outstanding thereunder.

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

We hold investments in Zebra (ownership 29%), Neovasc (1%), ChromaDex Corporation (0.1%), COCP (3%), NIMS (1%), Eloxx (2%), and BioCardia (1%). These investments were considered related party transactions as a result of our executive management's ownership interests and/or board representation in these entities. See further discussion of our investments in Note 6.

In November 2016, we entered into a Pledge Agreement with the Museum of Science, Inc. and the Museum of Science Endowment Fund, Inc. pursuant to which we agreed to contribute an aggregate of $1.0 million over a four-year period for constructing, equipping and the general operation of the Frost Science Museum. Dr. Frost and Mr. Richard Pfenniger serve on the Board of Trustees of the Frost Science Museum and Mr. Pfenniger is the Vice Chairman of the Board of Trustees.

We lease office space from Frost Real Estate Holdings, LLC ("Frost Holdings") in Miami, Florida, where our principal executive offices are located. Effective August 1, 2019, we entered into an amendment to our lease agreement with Frost Holdings. The lease, as amended, is for approximately 29,500 square feet of space. The lease provides for payments of approximately $89 thousand per month in the first year increasing annually to $101 thousand per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking.

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, 2021, we reimbursed approximately $0 thousand and $43 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2020, we reimbursed approximately $62 thousand and $156 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

NOTE 12 COMMITMENTS AND CONTINGENCIES

In connection with our acquisitions of CURNA, OPKO Diagnostics and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of September 30, 2021, we recorded $3.0 million as contingent consideration, with $0.5 million recorded within Accrued expenses and $2.5 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 5 and Note 17.

As previously reported, BioReference receives and is routinely required to respond to Civil Investigative Demands ("CID") in the ordinary course of business. On November 26, 2019, BioReference received a CID from the U.S. Department of Justice ("DOJ"). The CID states that DOJ is investigating whether BioReference paid unlawful remuneration to health care practitioners in violation of the Anti-Kickback Statute or Stark law and thus submitted or caused to be submitted false claims to government health care programs in violation of the False Claims Act. The time period covered by DOJ's requests is January 1, 2011 through November 26, 2019. BioReference has fully cooperated with the DOJ by submitting the requested information and making current employees available for interviews, and DOJ recently made a presentation to BioReference regarding its position. The parties have reached verbal agreement on the settlement amount, which is anticipated to be approximately $10 million, excluding attorney fees.

On April 5, 2019, former shareholders of Claros Diagnostics, Inc. filed a complaint in the Chancery Court of Delaware against the Company, alleging among other things, that the Company breached the Agreement and Plan of Merger dated October 13, 2011 by and among the Company, Claros Merger Subsidiary, LLC and Claros Diagnostics, Inc. (the "Merger Agreement"): (i) by failing to make a milestone payment of $2.375 million (payable in OPKO Common Stock) upon obtaining FDA approval of the Claros PSA test; and (ii) by repudiating its obligations to make additional future milestone payments as required under the Merger Agreement. In January 2021, the Company and the shareholder representative entered into a settlement agreement providing, among other things, that the Company pay the shareholders $1.2 million, which the Company has paid.

In April 2017, the Civil Division of the United States Attorney's Office for the Southern District of New York (the "SDNY") informed BioReference that it believed that, from 2008 to 2012, BioReference had, in violation of the False Claims Act, improperly billed Medicare and TRICARE (both are federal government healthcare programs) for clinical laboratory

services provided to hospital inpatient beneficiaries at certain hospitals. In April 2019, the SDNY also informed BioReference that it believed that BioReference provided physicians subsidies for electronic health record systems prior to 2012 that violated regulations adopted by HHS in 2006 which allowed laboratories to provide these donations under certain conditions. BioReference and the SDNY reached a settlement with respect to these matters and a final settlement and release, including BioReference's payment of an approximately $11.5 million settlement amount, was approved on September 22, 2020. The amount of related attorneys' fees is currently being negotiated.

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, 2021, we were committed to make future purchases for inventory and other items in 2021 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating approximately $223.7 million.

NOTE 13 REVENUE RECOGNITION

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

Revenue from services

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

The following are descriptions of our payors for laboratory services:

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

Government Payors. Reimbursements from government payors are based on fee-for-service schedules set by governmental authorities, including traditional Medicare and Medicaid. Revenues consist of amounts billed, net of contractual allowances for differences between amounts billed and the estimated consideration we expect to receive from such payors,

which considers historical denial and collection experience and the terms of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the government payors, are recorded upon settlement.

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

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

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as considerations unique to Medicare and Medicaid programs, require us to estimate the potential for retroactive adjustments as an element of variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known. For the nine months ended September 30, 2021, positive revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $36.0 million were recognized. For the nine months ended September 30, 2020, revenue reductions due to changes in estimates in implicit price concessions for performance obligations satisfied in prior periods of $1.6 million were recognized. Revenue adjustments for the nine months ended September 30, 2021 were primarily due to an improvement in COVID-19 test reimbursement estimates.

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, 2021 and December 31, 2020, we had liabilities of approximately $10.6 million and $14.9 million, respectively, within Accrued expenses and Other long-term liabilities related to reimbursements for payor overpayments.

The composition of Revenue from services by payor for the three and nine months ended September 30, 2021 and 2020 was as follows:

(In thousands)	Three months ended September 30, 2021	Three months ended September 30, 2020	Nine months ended September 30, 2021	Nine months ended September 30, 2020
Healthcare insurers	$ 117,892	$ 136,531	$ 391,771	$ 319,763
Government payers	48,204	21,537	179,473	64,322
Client payers	168,637	207,886	657,479	388,078
Patients	5,430	16,544	15,589	32,146
Total	$ 340,163	$ 382,498	$ 1,244,312	$ 804,309

Revenue from products

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

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

We recognize revenue for shipments of *Rayaldee* at the time of delivery to customers after estimating Sales Deductions and product returns as elements of variable consideration utilizing historical information and market research projections. For the three and nine months ended September 30, 2021, we recognized $8.5 million and $19.3 million, respectively, in net product revenue from sales of *Rayaldee.* For the three and nine months ended September 30, 2020, we recognized $8.1 million and $26.7 million, respectively, in net product revenue from sales of *Rayaldee.*

The following table presents an analysis of product sales allowances and accruals for the three and nine months ended September 30, 2021:

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at June 30, 2021	$ 1,701	$ 7,586	$ 3,324	$ 12,611
Provision related to current period sales	3,315	3,258	307	6,880
Credits or payments made	(3,616)	(6,733)	(405)	(10,754)
Balance at September 30, 2021	$ 1,400	$ 4,111	$ 3,226	$ 8,737
Total gross *Rayaldee* sales				$ 15,332
Provision for *Rayaldee* sales allowances and accruals as a percentage of gross *Rayaldee* sales				45%

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2020	$ 2,332	$ 5,812	$ 3,593	$ 11,737
Provision related to current period sales	10,854	16,013	942	27,809
Credits or payments made	(11,786)	(17,714)	(1,309)	(30,809)
Balance at September 30, 2021	$ 1,400	$ 4,111	$ 3,226	$ 8,737
Total gross *Rayaldee* sales				$ 47,099
Provision for *Rayaldee* sales allowances and accruals as a percentage of gross *Rayaldee* sales				59%

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

Revenue from intellectual property and other

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

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

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

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

Research and Development Activities: If we are entitled to reimbursement from our customers for specified research and development expenses, we account for them as separate performance obligations if distinct. We also determine whether the research and development funding would result in revenues or an offset to research and development expenses in accordance

with provisions of gross or net revenue presentation. The corresponding revenues or offset to research and development expenses are recognized as the related performance obligations are satisfied.

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

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

For the three months ended September 30, 2021, revenue from transfer of intellectual property principally and other reflects $2.5 million of revenue related to the Pfizer Transaction (as defined below), $1.0 million related to the LeaderMed (as defined below) joint venture and $4.9 million related to the CAMP4 Agreement (as defined below). For the nine months ended September 30, 2021, revenue from transfer of intellectual property and other principally reflects $8.1 million of revenue related to the Pfizer Transaction, $1.0 million related to the LeaderMed joint venture, $4.9 million related to the CAMP4 Agreement and a $5.0 million non-refundable upfront payment received under the Nicoya Agreement (as defined below). For the three and nine months ended September 30, 2020, revenue from transfer of intellectual property and other principally reflects $3.1 million and $25.8 million of revenue, respectively, related to the Pfizer Transaction. In addition, revenue from the transfer of intellectual property and other for the three and nine months ended September 30, 2020 includes grants of $10.0 million and $16.2 million, respectively, received by BioReference from the CARES Act. Refer to Note 14 for discussion of the Pfizer Transaction.

Contract liabilities relate to cash consideration that OPKO receives in advance of satisfying the related performance obligations.Changes in the contractual liabilities balance during the nine months ended September 30, 2021 are as follows:

(In thousands)		
Balance at December 31, 2020	$	16,378
Balance at September 30, 2021		3,362
Revenue recognized in the period from:		
Amounts included in contracts liability at the beginning of the period		13,016

The contract liability balance at September 30, 2021 related primarily to accelerated payments received as part of the CARES Act. Refer to Note 2.

NOTE 14 STRATEGIC ALLIANCES

LeaderMed

On September 14, 2021, we and LeaderMed Health Group Limited ("LeaderMed"), a pharmaceutical development company with operations based in Asia, announced the formation of a joint venture to develop, manufacture and commercialize two of OPKO's clinical stage, long-acting drug products in Greater China and eight other Asian territories.

Under the terms of the agreements, we have granted the joint venture exclusive rights to develop, manufacture and commercialize (a) OPK88003, an oxyntomodulin analog being developed for the treatment of obesity and diabetes, and (b) Factor VIIa-CTP, a novel long-acting coagulation factor being developed to treat hemophilia, in exchange for a 47% ownership interest in the joint venture. In addition, we received an upfront payment of $1 million and will be reimbursed for clinical trial material and technical support we provide the joint venture. For the three months ended September 30, 2021, we recognized the upfront payment of $1 million as revenue from transfer of intellectual property and other.

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

CAMP4 Therapeutics

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

We received an initial upfront payment of $1.5 million and 3,373,008 shares of CAMP4's Series A Prime Preferred Stock ("Preferred Stock"), which equates to approximately 9% of the outstanding shares of CAMP4, and we are eligible to receive up to $3.5 million in development milestone payments for Dravet syndrome products, and $4 million for non-Dravet syndrome products, as well as sales milestones of up to $90 million for Dravet syndrome products and up to $90 million for non-Dravet syndrome products. We may also receive double digit royalty payments on the net sales of royalty bearing products, subject to adjustment. In addition, upon achievement of certain development milestones, we will be eligible to receive equity consideration of up to 5,782,299 shares of Preferred Stock in connection with Dravet syndrome products and up to 1,082,248 shares of Preferred Stock in connection with non-Dravet syndrome products. In connection with our acquisition of CURNA, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result of our execution of the CAMP4 Agreement, we will have to pay a percentage of any payments received under the CAMP4 Agreement to the former CURNA stockholders. For the three months ended September 30, 2021, we recognized the fair value of the upfront payments of cash and shares of Preferred Stock totaling $4.9 million in revenue from transfer of intellectual property and other.

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

NICOYA Macau Limited

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

EirGen has received an initial upfront payment of $5 million and is eligible to receive an additional $5 million upon the first to occur of (A) a predetermined milestone and (B) the first anniversary of the effective date. 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 will also receive tiered, double digit royalty payments at rates in the low double digits on net product sales within the Nicoya Territory and in the Nicoya Field.

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

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

commercial sale in the Nicoya Territory. In addition to termination rights for material breach and bankruptcy, Nicoya is permitted to terminate the Nicoya Agreement after a specified notice period.

Vifor Fresenius Medical Care Renal Pharma Ltd

In May 2016, EirGen and VFMCRP entered into a Development and License Agreement (the "VFMCRP Agreement") for the development and commercialization of *Rayaldee* (the "Product") worldwide, except for (i) the U.S., (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 "VFMCRP Territory"), as amended. The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the Product in human patients (the "VFMCRP 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 "VFMCRP Initial Indication").

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

Effective May 5, 2020, we entered into an amendment to the VFMCRP Agreement pursuant to which the parties agreed to exclude Mexico, South Korea, the Middle East and all of the countries of Africa from the VFMCRP Territory. In addition, the parties agreed to certain amendments to the milestone structure and to reduce minimum royalties payable. As revised, the Company has received a $3 million payment triggered by the first marketing approval of *Rayaldee* in Europe and is eligible to receive up to an additional $17 million in regulatory milestones and $210 million in milestone payments tied to launch, pricing and sales of *Rayaldee*, and tiered, double-digit royalties.

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

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

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

Pfizer Inc.

In December 2014, we entered into an exclusive worldwide agreement (the "Pfizer Agreement") with Pfizer for the development and commercialization of our long-acting Somatrogon (hGH-CTP) for the treatment of growth hormone deficiency ("GHD") in adults and children, as well as for the treatment of growth failure in children born small for gestational age (the "Pfizer Transaction").

On September 24, 2021, we and Pfizer announced that the FDA extended the review period for the BLA for Somatrogon, a once-weekly long-acting recombinant human growth hormone, for the treatment of GHD in pediatric patients. The Prescription Drug User Fee Act ("PDUFA") goal date has been extended by three months to January 2022, as a result of

Pfizer's submission of additional data to the original BLA.

During the first quarter of 2021, regulatory submissions in the major global markets for Somatrogan have been accepted including, the U.S., European Medicines Agency, and Ministry of Health, Labour, and Welfare in Japan for Somatrogon for the treatment of pediatric patients with GHD.

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

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

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

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

We recognized the non-refundable $295.0 million upfront payments as revenue as the research and development services were completed and as of both September 30, 2021 and December 31, 2020, we had no contract liabilities related to the Pfizer Transaction.

The Pfizer Transaction includes milestone payments of $275.0 million upon the achievement of certain milestones. The milestones range from $20.0 million to $90.0 million each and are based on achievement of regulatory approval in the U.S. and regulatory approval and price approval in other major markets. The milestone payments will be recognized as revenue in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. To date, no revenue has been recognized related to the achievement of the milestones.

Pharmsynthez

In April 2013, we entered into a series of concurrent transactions with Pharmsynthez, a Russian pharmaceutical company traded on the Moscow Stock Exchange, pursuant to which we acquired an equity method investment in Pharmsynthez (ownership 9%). We also granted rights to certain technologies in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan (the "Pharmsynthez Territories") to Pharmsynthez and agreed to perform certain development activities. We will receive from Pharmsynthez royalties on net sales of products incorporating the technologies in the Pharmsynthez Territories, as well as a percentage of any sublicense income from third parties for the technologies in the Pharmsynthez Territories.

Other

We have completed strategic deals with numerous institutions and commercial partners. In connection with these agreements, upon the achievement of certain milestones we are obligated to make certain payments and have royalty obligations upon sales of products developed under the license agreements. At this time, we are unable to estimate the timing and amounts of payments as the obligations are based on future development of the licensed products.

NOTE 15 SEGMENTS

We manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of our pharmaceutical operations in Chile, Mexico, Ireland, Israel and Spain, *Rayaldee* product sales and our pharmaceutical research and development. The diagnostics segment primarily consists of our clinical and genomics laboratory operations through BioReference and our point-of-care operations. There are no significant inter-segment sales. We evaluate

the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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

	For the three months ended September 30,		For the nine months ended September 30,	
(In thousands)	2021	2020	2021	2020
Revenue from services:				
Pharmaceutical	$ —	$ —	$ —	$ —
Diagnostics	340,163	382,498	1,244,312	804,309
Corporate	—	—	—	—
	$ 340,163	$ 382,498	$ 1,244,312	$ 804,309
Revenue from products:				
Pharmaceutical	$ 36,882	$ 28,702	$ 106,490	$ 89,133
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ 36,882	$ 28,702	$ 106,490	$ 89,133
Revenue from transfer of intellectual property and other:				
Pharmaceutical	$ 8,768	$ 6,819	$ 22,585	$ 31,057
Diagnostics	—	10,045	—	16,240
Corporate	—	—	—	—
	$ 8,768	$ 16,864	$ 22,585	$ 47,297
Operating income (loss):				
Pharmaceutical	$ 28,617	$ (14,425)	$ (4,251)	$ (34,546)
Diagnostics	19,656	46,172	116,670	68,975
Corporate	(10,447)	(9,808)	(30,585)	(26,071)
	$ 37,826	$ 21,939	$ 81,834	$ 8,358
Depreciation and amortization:				
Pharmaceutical	$ 6,080	$ 7,316	$ 20,500	$ 21,556
Diagnostics	12,883	13,720	39,025	43,739
Corporate	—	—	—	—
	$ 18,963	$ 21,036	$ 59,525	$ 65,295
Loss from investment in investees:				
Pharmaceutical	$ (53)	$ (110)	$ (163)	$ (433)
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ (53)	$ (110)	$ (163)	$ (433)
Revenues:				
United States	$ 354,586	$ 400,778	$ 1,269,749	$ 847,539
Ireland	5,445	8,988	24,663	37,736
Chile	16,486	11,062	49,294	33,064
Spain	5,721	3,713	17,077	12,005
Israel	307	1,119	3,543	4,010
Mexico	3,162	2,280	8,619	5,987
Other	106	124	442	398
	$ 385,813	$ 428,064	$ 1,373,387	$ 940,739

(In thousands)	September 30, 2021	December 31, 2020
Assets:		
Pharmaceutical	$ 1,109,600	$ 1,176,245
Diagnostics	1,234,477	1,268,738
Corporate	73,561	28,080
	$ 2,417,638	$ 2,473,063
Goodwill:		
Pharmaceutical	$ 239,765	$ 245,793
Diagnostics	434,809	434,809
Corporate	—	—
	$ 674,574	$ 680,602

No customer represented more than 10% of our total consolidated revenue during the nine months ended September 30, 2021 and 2020. As of September 30, 2021 and December 31, 2020, 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 Consolidated Balance Sheet when the leases have terms of 12 months or less, and we elected not to separate nonlease components from lease components and instead account for each separate lease component and the nonlease components associated with that lease component as a single lease component.

The following table presents the lease balances within the Condensed Consolidated Balance Sheet as of September 30, 2021 and December 31, 2020:

(in thousands)	Classification on the Balance Sheet	September 30, 2021	December 31, 2020
Assets			
Operating lease assets	Operating lease right-of-use assets	$ 33,502	$ 37,735
Finance lease assets	Property, plant and equipment, net	4,111	5,258
Liabilities			
Current			
Operating lease liabilities	Current maturities of operating leases	9,823	9,028
Accrued expenses	Current maturities of finance leases	1,809	2,453
Long-term			
Operating lease liabilities	Operating lease liabilities	28,256	29,760
Other long-term liabilities	Finance lease liabilities	$ 2,302	$ 2,805
Weighted average remaining lease term			
Operating leases		5.7 years	5.4 years
Finance leases		2.4 years	2.3 years
Weighted average discount rate			
Operating leases		5.6 %	5.8 %
Finance leases		6.2 %	3.6 %

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, 2021:

(in thousands)	Operating	Finance
October 1, 2021 through December 31, 2021	$ 1,454	$ 671
2022	11,254	1,658
2023	7,939	1,063
2024	5,749	723
2025	3,726	247
Thereafter	16,361	4
Total undiscounted future minimum lease payments	46,483	4,366
Less: Difference between lease payments and discounted lease liabilities	8,404	255
Total lease liabilities	$ 38,079	$ 4,111

Expense under operating leases and finance leases was $13.4 million and $1.7 million, respectively, for the three and nine months ended September 30, 2021, which includes $1.4 million of variable lease costs. Expense under operating leases and finance leases was $13.7 million and $2.3 million, respectively, for the three and nine months ended September 30, 2020, which includes $2.3 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,	
	2021	2020
Operating cash out flows from operating leases	$ 12,278	$ 13,596
Operating cash out flows from finance leases	101	149
Financing cash out flows from finance leases	1,498	2,009
Total	$ 13,877	$ 15,754

NOTE 17 SUBSEQUENT EVENTS

We have reviewed all events and transactions that occurred subsequent to September 30, 2021 and prior to the time of filing this Quarterly Report on Form 10-Q and determined that no such events required disclosure to or adjustment in the September 30, 2021 Condensed Consolidated Financial Statements.

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, 2020 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part I, Item 1A of the Form 10-K and as described from time to time in our other filings with the Securities and Exchange Commission. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories, Inc. ("BioReference"), one of the nation's largest full service laboratories with a core genetic testing business and an almost 300-person sales and marketing team to drive growth and leverage new products, including the *4Kscore* test. Our pharmaceutical business features *Rayaldee*, a U.S. Food and Drug Administration ("FDA") approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency and a pipeline of products in various stages of development. Our leading product in development is Somatrogon (hGH-CTP), a once-weekly human growth hormone for which we have partnered with Pfizer, Inc. ("Pfizer") and successfully completed a phase 3 study in August 2019, and for which the FDA has accepted the initial Biologics License Application ("BLA") for filing. We also submitted a New Drug Application (an "NDA") with the Ministry of Health, Labour and Welfare in Japan and a Marketing Authorization Application with the European Medicines Agency.We are incorporated in Delaware, and our principal executive offices are located in leased offices in Miami, Florida.

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

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

RECENT DEVELOPMENTS

On September 24, 2021, we and Pfizer announced that the FDA extended the review period for the BLA for Somatrogon, a once-weekly long-acting recombinant human growth hormone, for the treatment of GHD in pediatric patients. The PDUFA goal date has been extended by three months to January 2022, as a result of Pfizer's submission of additional data to the original BLA.

On September 14, 2021, we and LeaderMed, a pharmaceutical development company with operations based in Asia, 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 our agreements with LeaderMed, we have granted the joint venture exclusive rights to develop, manufacture and commercialize (a) OPK88003, an oxyntomodulin analog being developed for the treatment of obesity and diabetes, and (b) Factor VIIa-CTP, a novel long-acting coagulation factor being developed to treat hemophilia, in exchange for a 47% ownership interest in the joint venture. In addition, we received an upfront payment of $1 million and will be reimbursed for clinical trial material and technical support it provides the joint venture.

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

On August 30, 2021, we announced the completion of enrollment in our Phase 2 trial with *Rayaldee* as a treatment for mild-to-moderate COVID-19. The U.S. trial, "A Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Safety and Efficacy of Rayaldee (calcifediol) Extended-release Capsules to Treat Symptomatic Patients Infected with SARS-CoV-2 (REsCue)," was expected to enroll approximately 160 subjects, including some with stage 3 or 4 chronic kidney disease (CKD) who are at higher risk for developing more severe illness. Final enrollment reached 171 subjects and topline data are expected later this year.

On August 16, 2021, BioReference announced the acquisition of Ariosa Diagnostics, Inc. ("Ariosa"), the U.S. Ariosa centralized laboratory prenatal testing business from Roche Molecular Systems Inc. Ariosa's non invasive prenatal screening (NIPS) test, the Harmony Prenatal Test, is one of the most widely studied tests utilized in prenatal screening. The test has been performed in over 1.5 million patients. BioReference currently offers, ClariTest™ Core, which utilizes the same core technology as the Harmony Prenatal Test. The acquisition of Ariosa will complement our current NIPS offering.

RESULTS OF OPERATIONS

Impact of COVID-19

As the disease caused by SARS-CoV-2, a novel strain of coronavirus, COVID-19 continues to spread and severely impact the U.S. economy and economies of other countries around the world, we continue to be a part of the coordinated public and private sector response to this unprecedented challenge as the COVID-19 pandemic continues. There continues to be a high level of uncertainty relating to how the pandemic will evolve, how governments and consumers will react, progress on the distribution of vaccines and whether the pandemic will have a longer-term effect on the healthcare industry and patient habits. In response to the COVID-19 pandemic, BioReference is providing COVID-19 solutions, including diagnostic molecular testing and serology antibody testing, to meet the testing needs of its numerous customer verticals, including physicians, health systems, long-term care facilities, governments, schools, employers, professional sports teams and entertainment venues, as wells as the general public through relationships with retail pharmacy chains.

Revenue from services for the three months ended September 30, 2021 decreased by $42.3 million as compared to 2020 due to a decline in COVID-19 testing volumes. We are unable to predict how long the demand will continue for our COVID-19 related testing, or whether pricing and reimbursement policies for testing will sustain. In addition, overall demand for COVID-19 testing has recently declined, and accordingly, the sustainability of our COVID-19 testing volumes is uncertain. Additionally, beginning in March 2020, BioReference experienced a decline in testing volumes due to the COVID-19 pandemic; however as stay at home orders and other restrictions have been lifted, we have seen our routine clinical and genomic testing volumes trending towards normalization with prior periods. Should stay at home orders or other restrictions be reenacted, we could see our routine testing levels decline. Excluding COVID-19 test volumes, for the three months ended September 30, 2021, genomic and routine clinical test volume increased 19.1% and 0.7% as compared to volumes for the three months ended September 30, 2020. Additionally, sales of *Rayaldee* have not increased in accordance with its expected growth trajectory as a result of challenges in onboarding new patients due to the COVID-19 pandemic. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, customers closing or severely curtailing their operations (voluntarily or in response to government orders), and the adoption of work-from-home or shelter-in-place policies.

In March 2020, in response to the COVID-19 pandemic, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law. The CARES Act provides numerous tax provisions and other stimulus measures, including temporary changes regarding the prior and future utilization of net operating losses, temporary changes to the prior and future limitations on interest deductions, temporary suspension of certain payment requirements for the employer portion of Social Security taxes, technical corrections from prior tax legislation for tax depreciation of certain qualified improvement property, and the creation of certain payroll tax credits associated with the retention of employees.

We have received, or expect to receive a number of benefits under the CARES Act including, but not limited to:

- During the second quarter of 2020, we received approximately $14 million under The Centers for Medicare & Medicaid Services (CMS) Accelerated and Advance Payment Program, which provides accelerated payments to Medicare providers/suppliers working to provide treatment to patients and combat the COVID-19 pandemic, and the amounts advanced are loans which will be offset against future claims and must be repaid in 2021. These loans are initially recorded as contract liabilities included in Accrued expenses and are reduced as the amounts are recouped by CMS;
- We were eligible to defer depositing the employer's share of Social Security taxes for payments due from March 27, 2020 through December 31, 2020, interest-free and penalty-free;
- We received approximately $16.2 million during 2020 from the funds that were distributed to healthcare providers for related expenses or lost revenues that are attributable to the COVID-19 pandemic;
- U.S. Department of Health and Human Services (HHS), will provide claims reimbursement to healthcare providers generally at Medicare rates for testing uninsured patients; and
- Clinical laboratories are provided a one-year reprieve from the reporting requirements under the Protecting Access to Medicare Act ("PAMA") as well as a one-year delay of reimbursement rate reductions for clinical laboratory services provided under Medicare that were scheduled to take place in 2021.

Since the pandemic began in the U.S., we have invested in testing capabilities and infrastructure to meet demand for our molecular and antibody testing for COVID-19. In 2021, we kicked off company wide lab operations specimen acquisition,

logistics, procurement, customer service, cost reduction initiatives to rightsize our cost structure to match the declining COVID testing volumes and to drive efficiency gains in our core clinical lines of business.

Three vaccines for COVID-19 have received approval or emergency authorization and have had increasingly widespread acceptance. However, we believe that, based on our experience with the pandemic, the high medical need for efficient and widespread testing for COVID-19 will extend beyond the current phase of the pandemic. Our belief is supported by the unprecedented healthcare and economic impact of the pandemic thus far, the uneven and incomplete rollout of vaccines and the fact that significant portions of the U.S. population may never be vaccinated, and the continued likelihood of surges of COVID-19 including from new strains of SARS-CoV-2 with uncertain susceptibility to the current vaccines. We believe that these factors have greatly magnified the need for more effective therapeutics and the need for efficient and widespread testing, with properties targeted to the disease processes caused by serious viral infections.

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

Our consolidated income (loss) from operations for the three months ended September 30, 2021 and 2020 is as follows:

	For the three months ended September 30,			
(In thousands)	2021	2020	Change	% Change
Revenues:				
Revenue from services	$ 340,163	$ 382,498	$ (42,335)	(11)%
Revenue from products	36,882	28,702	8,180	28 %
Revenue from transfer of intellectual property and other	8,768	16,864	(8,096)	(48)%
Total revenues	385,813	428,064	(42,251)	(10)%
Costs and expenses:				
Cost of revenue	243,957	272,773	(28,816)	(11)%
Selling, general and administrative	105,120	99,897	5,223	5 %
Research and development	18,306	18,493	(187)	(1)%
Contingent Consideration	(497)	1,083	(1,580)	(146)%
Amortization of intangible assets	12,609	13,879	(1,270)	(9)%
Gain on sale of assets	(31,508)	—	(31,508)	— %
Total costs and expenses	347,987	406,125	(58,138)	(14)%
Income from operations	37,826	21,939	15,887	72 %

Diagnostics

(In thousands)	For the three months ended September 30, 2021	2020	Change	% Change
Revenues				
Revenue from services	$ 340,163	$ 382,498	$ (42,335)	(11)%
Revenue from transfer of intellectual property and other	—	10,045	(10,045)	(100)%
Total revenues	340,163	392,543	(52,380)	(13)%
Costs and expenses:				
Cost of revenue	223,195	255,341	(32,146)	(13)%
Selling, general and administrative	83,723	78,008	5,715	7 %
Research and development	5,894	4,170	1,724	41 %
Contingent Consideration	—	36	(36)	(100)%
Amortization of intangible assets	7,695	8,816	(1,121)	(13)%
Total costs and expenses	320,507	346,371	(25,864)	(7)%
Income from operations	19,656	46,172	(26,516)	(57)%

Revenue. Revenue from services for the three months ended September 30, 2021 decreased by approximately $42.3 million compared to the three months ended September 30, 2020. BioReference recognized a decrease in revenue for the three months ended September 30, 2021 compared to the three months ended September 30, 2020 due to a decrease in COVID-19 testing volume of $92.2 million, which was partially offset by an improvement in COVID-19 test reimbursement of $7.3 million. BioReference performed 2.2 million diagnostic molecular tests for COVID-19 and 0.2 million serology antibody tests during the three months ended September 30, 2021, which represented 51.7% of total volume for that period. In comparison, the three months ended September 30, 2020 included 3.5 million molecular tests for COVID-19 and 0.3 million serology antibody tests.

Partially offsetting the decrease in COVID-19 test volumes were increases in clinical test volume and genomic test volume of $1.0 million and $4.6 million, respectively, and an increase in realized clinical and genomic test reimbursement of $21.0 million and $5.9 million, respectively.

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, 2021 positive revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $0.4 million were recognized. For the three months ended September 30, 2020, revenue reductions due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $1.7 million were recognized. Revenue adjustments for the three months ended September 30, 2021 were primarily due to an improvement in COVID-19 test reimbursement estimates.

The composition of Revenue from services by payor for the three months ended September 30, 2021 and 2020 was as follows:

(In thousands)	Three months ended September 30, 2021	2020
Healthcare insurers	$ 117,892	$ 136,531
Government payers	48,204	21,537
Client payers	168,637	207,886
Patients	5,430	16,544
Total	$ 340,163	$ 382,498

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

Revenue from the transfer of intellectual property and other for the three months ended September 30, 2020 are the result of grants received under the CARES Act totaling $10.0 million.

Cost of revenue. Cost of revenue for the three months ended September 30, 2021 decreased $32.1 million compared to the three months ended September 30, 2020. Cost of revenue decreased primarily due to a decline in the volume of COVID-19 tests performed during the three months ended September 30, 2021 compared to 2020. Cost of revenue for the three months ended September 30, 2021 also decreased due to changes in the product mix of items sold during the period and due to a $5.5 million sales and use tax credit received during the period.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2021 and 2020 were $83.7 million and $78.0 million, respectively. Selling, general and administrative expenses in our diagnostics segment increased primarily due to increased investment in our commercial digital organization resulting in higher professional fees and personnel expenses. We are in the process of implementing company wide cost reduction initiatives to rightsize our cost structure to match the declining COVID testing volumes and to drive efficiency gains in our core clinical lines of business.

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

Research and Development Expenses	Three months ended September 30,	
	2021	2020
External expenses:		
PMA studies	$ —	$ 53
Research and development employee-related expenses	4,870	2,522
Other internal research and development expenses	1,024	1,595
Total research and development expenses	$ 5,894	$ 4,170

The increase in research and development expenses for the three months ended September 30, 2021 resulted primarily related to the development of clinical and genomics testing services.

Contingent consideration. Contingent consideration for the three months ended September 30, 2021 and 2020 was $0.0 thousand and $36.0 thousand of expense, respectively. Contingent consideration for the three months ended September 30, 2020 was attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Diagnostics, and potential amounts payable to former stockholders of OPKO Diagnostics in connection therewith, pursuant to our acquisition agreement in October 2011.

Amortization of intangible assets. Amortization of intangible assets was $7.7 million and $8.8 million, respectively, for the three months ended September 30, 2021 and 2020. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization expense declined during the three months ended September 30, 2021 due to acquired intangible assets becoming fully amortized.

Pharmaceuticals

(In thousands)	For the three months ended September 30, 2021	2020	Change	% Change
Revenues:				
Revenue from products	$ 36,882	$ 28,702	$ 8,180	28 %
Revenue from transfer of intellectual property and other	8,768	6,819	1,949	29 %
Total revenues	45,650	35,521	10,129	29 %
Costs and expenses:				
Cost of revenue	20,772	17,464	3,308	19 %
Selling, general and administrative	10,452	11,824	(1,372)	(12)%
Research and development	12,900	14,548	(1,648)	(11)%
Contingent Consideration	(497)	1,047	(1,544)	(147)%
Amortization of intangible assets	4,914	5,063	(149)	(3)%
Gain on sale of assets	(31,508)	—	(31,508)	(100)%
Total costs and expenses	17,033	49,946	(32,913)	(66)%
Income (loss) from operations	28,617	(14,425)	43,042	(298)%

Revenue. The increase in revenue from products for the three months ended September 30, 2021 compared to the three months ended September 30, 2020 was primarily attributable to an increase in sales at most of our international operating companies. Revenue from sales of *Rayaldee* for the three months ended September 30, 2021 and 2020 was $8.5 million and $8.1 million, respectively. Sales of *Rayaldee* in 2020 and 2021 have been negatively impacted as a result of challenges in onboarding new patients due to the COVID-19 pandemic. Revenue from transfer of intellectual property and other for the three months ended September 30, 2021 and 2020 reflect $2.5 million and $3.1 million, respectively, of revenue related to the Pfizer Transaction. Revenue from transfer of intellectual property and other for the three months ended September 30, 2021 also reflect $4.9 million related to the CAMP4 Agreement.

Cost of revenue. Cost of revenue for the three months ended September 30, 2021 increased $3.3 million compared to the three months ended September 30, 2020 primarily due to an increase in inventory and material costs at most of our international operating companies, which was due to the increase in sales at our international operating companies.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2021 and 2020 were $10.5 million and $11.8 million, respectively. The decrease in selling, general and administrative expenses was primarily due to an decrease in professional fees and laboratory costs at EirGen. Selling, general and administrative expenses for the pharmaceutical segment for the three months ended September 30, 2021 and 2020 included equity-based compensation expense of $0.3 million and $0.6 million, respectively.

Research and development expenses. Research and development expenses for the three months ended September 30, 2021 and 2020 were $12.9 million and $14.5 million, respectively. Research and development expenses include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by 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	Three months ended September 30,	
	2021	2020
External expenses:		
Manufacturing expense for biological products	$ 1,305	$ 2,526
Phase III studies	2,126	2,646
Post-marketing studies	27	81
Earlier-stage programs	3,160	3,549
Research and development employee-related expenses	5,084	5,349
Other internal research and development expenses	631	2,410
Third-party grants and funding from collaboration agreements	567	(2,013)
Total research and development expenses	$ 12,900	$ 14,548

The decrease in research and development expenses for the three months ended September 30, 2021 was primarily due to a decrease in research and development expenses for Somatrogon, a once-weekly human growth hormone injection for which we have partnered with Pfizer and successfully completed a phase 3 study in August 2019. Ongoing expenses on the Somatrogon program support open label extension studies that will continue until market launch of Somatrogon in certain countries, as well as the preparation of applications for marketing approvals. Research and development expenses for the pharmaceutical segment for the three months ended September 30, 2021 and 2020 included equity-based compensation expense of $0.3 million and $0.7 million, respectively.

Contingent consideration. Contingent consideration for the three months ended September 30, 2021 and 2020 was $0.5 million reversal of expense and $1.0 million of expense, respectively. Contingent consideration for the three months ended September 30, 2021 and 2020 was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal, and potential amounts payable to former stockholders of OPKO Renal in connection therewith, pursuant to our acquisition agreement in March 2013.

Amortization of intangible assets. Amortization of intangible assets was $4.9 million and $5.1 million, respectively, for the three months ended September 30, 2021 and 2020. 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.

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

Corporate

(In thousands)	For the three months ended September 30, 2021	2020	Change	% Change
Costs and expenses:				
Cost of revenue	$ (10)	$ (32)	$ 22	(69)%
Selling, general and administrative	10,945	10,065	880	9 %
Research and development	(488)	(225)	(263)	117 %
Total costs and expenses	10,447	9,808	639	7 %
Loss from operations	(10,447)	(9,808)	(639)	7 %

Operating loss for our unallocated corporate operations for the three months ended September 30, 2021 and 2020 was $10.4 million and $9.8 million, respectively, and principally reflect general and administrative expenses incurred in connection with our corporate operations. Operating loss for our unallocated corporate operations for the three months ended September 30, 2021 was consistent with the comparable period of 2020.

Other

Interest income. Interest income for the three months ended September 30, 2021 and 2020 was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

Interest expense. Interest expense for the three months ended September 30, 2021 and 2020 was $4.3 million and $5.5 million, respectively. Interest expense was principally related to interest incurred on the 2025 Notes, the 2023 Convertible Notes, the 2033 Senior Notes, and BioReference's outstanding debt under the A&R Credit Agreement.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended September 30, 2021 and 2020, was $1.3 million of income and $0.5 million of expense, respectively. Derivative income for the three months ended September 30, 2021, was principally related to the change in fair value on foreign currency forward exchange contracts at OPKO Chile.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2021 and 2020, was $3.4 million of expense and $4.7 million of income, respectively. Other expense for the three months ended September 30, 2021 primarily consisted of net unrealized losses recognized during the period on our investments in our equity securities. Other income for the three months ended September 30, 2020 primarily consisted of realized gains recognized during the period on sales of our investment in VBI.

Income tax benefit (provision). Our income tax provision for the three months ended September 30, 2021 and 2020 was $(2.7) million and $3.2 million, respectively, and reflects quarterly results using our expected effective tax rate. For the three months ended September 30, 2021, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in certain early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report net losses. Loss from investments in investees was $0.1 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

Our consolidated income (loss) from operations for the nine months ended September 30, 2021 and 2020 is as follows:

(In thousands)	For the nine months ended September 30, 2021	2020	Change	% Change
Revenues:				
Revenue from services	$ 1,244,312	$ 804,309	$ 440,003	55 %
Revenue from products	106,490	89,133	17,357	19 %
Revenue from transfer of intellectual property and other	22,585	47,297	(24,712)	(52)%
Total revenues	1,373,387	940,739	432,648	46 %
Costs and expenses:				
Cost of revenue	900,371	575,683	324,688	56 %
Selling, general and administrative	330,643	253,749	76,894	30 %
Research and development	55,843	57,862	(2,019)	(3)%
Contingent Consideration	(1,556)	1,334	(2,890)	(217)%
Amortization of intangible assets	37,760	43,753	(5,993)	(14)%
Gain on sale of assets	(31,508)	—	(31,508)	(100)%
Total costs and expenses	1,291,553	932,381	359,172	39 %
Income from operations	81,834	8,358	73,476	879 %

Diagnostics

(In thousands)	For the nine months ended September 30, 2021	2020	Change	% Change
Revenues				
Revenue from services	$ 1,244,312	$ 804,309	$ 440,003	55 %
Revenue from transfer of intellectual property and other	—	16,240	(16,240)	(100)%
Total revenues	1,244,312	820,549	423,763	52 %
Costs and expenses:				
Cost of revenue	830,428	523,029	307,399	59 %
Selling, general and administrative	260,850	188,445	72,405	38 %
Research and development	13,548	11,348	2,200	19 %
Contingent Consideration	—	104	(104)	(100)%
Amortization of intangible assets	22,816	28,648	(5,832)	(20)%
Total costs and expenses	1,127,642	751,574	376,068	50 %
Income from operations	116,670	68,975	47,695	69 %

Revenue. Revenue from services for the nine months ended September 30, 2021 increased by approximately $440.0 million compared to the nine months ended September 30, 2020. BioReference recognized an increase in revenue for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 due to an improvement in clinical test reimbursement, and an increase in clinical test volume and genomic test volume of $30.8 million, $34.0 million and $19.4 million, respectively. This was partially offset by the negative impact of a reduction in genomic test reimbursement of $11.9 million.

BioReference also recognized an increase in revenue for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 due to an increase in COVID-19 testing volume and improvement in COVID-19 test reimbursement of $197.8 million and $153.8 million, respectively. BioReference performed 9.1 million diagnostic molecular tests for COVID-19 and 0.5 million serology antibody tests during the nine months ended September 30, 2021, which represented 59.6% of total volume for that period. In comparison, the nine months ended September 30, 2020 included 5.8 million molecular tests for COVID-19 and 0.6 million serology antibody tests.

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, 2021, positive revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $36.0 million were recognized. For the nine months ended September 30, 2020, revenue reductions due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $1.6 million were recognized. Revenue adjustments for the nine months ended September 30, 2021 were primarily due to an improvement in COVID-19 test reimbursement estimates.

The composition of Revenue from services by payor for the nine months ended September 30, 2021 and 2020 was as follows:

	Nine months ended September 30,	
(In thousands)	2021	2020
Healthcare insurers	$ 391,771	$ 319,763
Government payers	179,473	64,322
Client payers	657,479	388,078
Patients	15,589	32,146
Total	$ 1,244,312	$ 804,309

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

Revenue from the transfer of intellectual property and other for the nine months ended September 30, 2020 are the result of grants received under the CARES Act totaling $16.2 million.

Cost of revenue. Cost of revenue for the nine months ended September 30, 2021 increased $307.4 million compared to the nine months ended September 30, 2020. Cost of revenue increased primarily due to labor and material costs for COVID-19 testing and the significant volume of tests performed during the nine months ended September 30, 2021. Cost of revenue for the nine months ended September 30, 2021 also increased due to changes in the product mix of items sold during the period, which was partially offset by a $5.5 million sales and use tax credit received during the nine months ended September 30, 2021.

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2021 and 2020 were $260.9 million and $188.4 million, respectively. Selling, general and administrative expenses in our diagnostics segment increased primarily due to higher variable billing and compensation costs from an increase in volume and collections during the nine months ended September 30, 2021, and in marketing costs and other administrative costs directly associated with COVID-19 testing volumes. Selling, general and administrative expenses for the nine months ended September 30, 2021 also include $6.2 million of expense incurred in connection with certain legal matters. As a percentage of net revenue from services, selling, general and administrative expenses for the diagnostic segment decreased to 21% from 23% for the nine months ended September 30, 2021 and 2020, respectively, as a result of per requisition efficiencies and continued execution of appropriate expense management during the period.

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,	
	2021	2020
External expenses:		
PMA studies	$ 31	$ 164
Research and development employee-related expenses	9,992	6,895
Other internal research and development expenses	3,525	4,289
Total research and development expenses	$ 13,548	$ 11,348

The increase in research and development expenses for the nine months ended September 30, 2021 resulted primarily from an increased research and development expenses related to the development of clinical and genomics testing services.

Contingent consideration. Contingent consideration for the nine months ended September 30, 2021 and 2020 was $0 thousand and $104 thousand of expense, respectively. Contingent consideration for the nine months ended September 30, 2020

was attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Diagnostics, andpotential amounts payable to former stockholders of OPKO Diagnostics in connection therewith, pursuant to our acquisition agreement in October 2011.

Amortization of intangible assets. Amortization of intangible assets was $22.8 million and $28.6 million, respectively, for the nine months ended September 30, 2021 and 2020. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization expense declined during the nine months ended September 30, 2021 due to acquired intangible assets becoming fully amortized.

Pharmaceuticals

	For the nine months ended September 30,			
(In thousands)	2021	2020	Change	% Change
Revenues:				
Revenue from products	$ 106,490	$ 89,133	$ 17,357	19 %
Revenue from transfer of intellectual property and other	22,585	31,057	(8,472)	(27)%
Total revenues	129,075	120,190	8,885	7 %
Costs and expenses:				
Cost of revenue	69,973	52,758	17,215	33 %
Selling, general and administrative	37,978	38,493	(515)	(1)%
Research and development	43,495	47,150	(3,655)	(8)%
Contingent Consideration	(1,556)	1,230	(2,786)	(227)%
Amortization of intangible assets	14,944	15,105	(161)	(1)%
Gain on sale of assets	(31,508)	—	(31,508)	(100)%
Total costs and expenses	133,326	154,736	(21,410)	(14)%
Loss from operations	(4,251)	(34,546)	30,295	(88)%

Revenue. The increase in revenue from products for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 was primarily attributable to an increase in sales at most of our international operating companies. Revenue from sales of *Rayaldee* for the nine months ended September 30, 2021 and 2020 was $19.3 million and $26.7 million, respectively. Sales of *Rayaldee* have been negatively impacted as a result of challenges in onboarding new patients due to the COVID-19 pandemic. Revenue from transfer of intellectual property and other for the nine months ended September 30, 2021 and 2020 reflect $8.1 million and $25.8 million, respectively, of revenue related to the Pfizer Transaction. Revenue from transfer of intellectual property and other for the nine months ended September 30, 2021 also includes a $5.0 million non-refundable upfront payment we received under the license agreement with Nicoya Therapeutics and $4.9 million related to the CAMP4 Agreement.

Cost of revenue. Cost of revenue for the nine months ended September 30, 2021 increased $17.2 million compared to the nine months ended September 30, 2020. Cost of product revenue increased primarily due to an increase in inventory and material costs at most of our international operating companies, which was due to the increase in sales at our international operating companies and to a $3.6 million inventory reserve recognized for *Rayaldee* inventory for the nine months ended September 30, 2021. This was partially offset by a decrease in sales of *Rayaldee* for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020.

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2021 and 2020 were $38.0 million and $38.5 million, respectively. Selling, general and administrative expenses for the nine months ended September 30, 2021 was consistent with selling, general and administrative expenses for the nine months ended September 30, 2020. Selling, general and administrative expenses for the pharmaceutical segment for the nine months ended September 30, 2021 and 2020 included equity-based compensation expense of $1.0 million and $2.0 million, respectively.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2021 and 2020 were $43.5 million and $47.2 million, respectively. Research and development expenses include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and premarket approval for diagnostics tests, if any. Internal expenses include employee-related expenses such as salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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

Research and Development Expenses	Nine months ended September 30,	
	2021	2020
External expenses:		
Manufacturing expense for biological products	$ 3,785	$ 5,254
Phase III studies	7,137	7,985
Post-marketing studies	54	1,203
Earlier-stage programs	13,194	11,117
Research and development employee-related expenses	15,834	16,617
Other internal research and development expenses	2,948	6,987
Third-party grants and funding from collaboration agreements	543	(2,013)
Total research and development expenses	$ 43,495	$ 47,150

The decrease in research and development expenses for the nine months ended September 30, 2021 was primarily due to a decrease in research and development expenses related to Somatrogon, a once-weekly human growth hormone injection for which we have partnered with Pfizer and successfully completed a phase 3 study in August 2019. Ongoing expenses on the Somatrogon program support open label extension studies that will continue until market launch of Somatrogon in certain countries, as well as the preparation of applications for marketing approvals. Research and development expenses for the pharmaceutical segment for the nine months ended September 30, 2021 and 2020 included equity-based compensation expense of $1.0 million and $1.3 million, respectively.

Contingent consideration. Contingent consideration for the nine months ended September 30, 2021 and 2020 was $1.6 million reversal of expense and $1.2 million of expense, respectively. Contingent consideration for the nine months ended September 30, 2021 was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal and OPKO CURNA, and potential amounts payable to former stockholders of OPKO Renal and OPKO CURNA in connection therewith, pursuant to our acquisition agreements in March 2013 and January 2011, respectively. Contingent consideration for the nine months ended September 30, 2020 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.

Amortization of intangible assets. Amortization of intangible assets was $14.9 million and $15.1 million, respectively, for the nine months ended September 30, 2021 and 2020. 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.

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

Corporate

(In thousands)	For the nine months ended September 30, 2021	2020	Change	% Change
Costs and expenses:				
Cost of revenue	$ (30)	$ (104)	$ 74	(71)%
Selling, general and administrative	31,815	26,811	5,004	19 %
Research and development	(1,200)	(636)	(564)	89 %
Total costs and expenses	30,585	26,071	4,514	17 %
Loss from operations	(30,585)	(26,071)	(4,514)	17 %

Operating loss for our unallocated corporate operations for the nine months ended September 30, 2021 and 2020 was $30.6 million and $26.1 million, respectively. Total costs and expenses for the nine months ended September 30, 2021 principally reflect general and administrative expenses incurred in connection with our corporate operations. The increase in total costs and expenses for the nine months ended September 30, 2021 was primarily attributable to an increase in legal fees incurred for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

Other

Interest income. Interest income for the nine months ended September 30, 2021 and 2020 was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

Interest expense. Interest expense for the nine months ended September 30, 2021 and 2020 was $14.6 million and $16.5 million, respectively. Interest expense was principally related to interest incurred on the 2025 Notes, the 2023 Convertible Notes, the 2033 Senior Notes, and BioReference's outstanding debt under the A&R Credit Agreement (as defined below).

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the nine months ended September 30, 2021 and 2020, was $0.6 million and $0.1 million reversal of expense, respectively. Fair value changes of derivative instruments for the nine months ended September 30, 2021 and 2020, was principally related to the change in fair value on foreign currency forward exchange contracts at OPKO Chile.

Other income (expense), net. Other income (expense), net for the nine months ended September 30, 2021 and 2020, was $16.1 million of expense and $10.6 million of income, respectively. Other expense for the nine months ended September 30, 2021 primarily consisted of a $11.1 million non-cash loss related to the exchange of $55.4 million of the outstanding 2025 Notes for 19,051,270 shares of our Common Stock and net unrealized losses recognized during the period on our investments in our equity securities. Other income for the nine months ended September 30, 2020 primarily consisted of realized and unrealized gains recognized during the period on our investment in VBI, offset by net unrealized losses recognized during the period on our investment in Eloxx.

Income tax provision. Our income tax provision for the nine months ended September 30, 2021 and 2020 was $8.0 million and $4.0 million, respectively, and reflects quarterly results using our expected effective tax rate. For the nine months ended September 30, 2021, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in certain early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report net losses. Loss from investments in investees was $163 thousand and $433 thousand for the nine months ended September 30, 2021 and 2020, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2021, we had cash and cash equivalents of approximately $148.6 million. Cash provided by operations of $44.0 million for the nine months ended September 30, 2021 principally reflects cash generated by our diagnostics segment due to the positive impact of COVID-19 testing volumes, which was partially offset by general and administrative expenses related to our corporate operations and research and development activities. Cash provided by investing activities for the nine months ended September 30, 2021 primarily reflects $66.0 million from the sale of property, plant and equipment, which was partially offset by capital expenditures of $25.4 million. Cash used in financing activities of $11.2 million primarily reflects net repayments on our lines of credit. We have historically not generated sustained positive cash flow sufficient to offset our operating and other expenses, and our primary sources of cash have been from the public and private placement of equity, the issuance of the 2033 Senior Notes, 2023 Convertible Notes and 2025 Notes and credit facilities available to us. However, as a result of the significant increase in testing volumes resulting from the COVID-19 pandemic, we have generated positive cash flow from operations; however we are unable to predict how long the demand will continue for our COVID-19 related testing, or whether pricing and reimbursement policies for testing will sustain, and accordingly, the sustainability of our cash flows from operations. Overall demand for COVID-19 testing has recently declined, and accordingly, the sustainability of our COVID-19 testing volumes is uncertain. We are unable to predict how long the demand will continue for our COVID-19 related testing, whether pricing and reimbursement policies for testing will sustain, or whether further restrictions will be placed on elective procedures or if stay at home orders will be reinstated and accordingly, the sustainability of the cash flow is uncertain.

In June 2021, EirGen Pharma Limited ("EirGen"), our wholly owned subsidiary, entered into a definitive agreement to sell one of its facilities in Waterford, Ireland to Horizon Therapeutics plc for $65 million in cash less certain assumed and accrued liabilities relating to transferred employees. The facility, which was formerly included in our pharmaceutical segment, housed EirGen's sterile-fill-finish business and was no longer a core component of our ongoing operations and business strategy. The transaction closed in the third quarter of 2021.

On February 25, 2020, we entered into a credit agreement with an affiliate of Dr. Frost, pursuant to which the lender committed to provide us with an unsecured line of credit in the amount of $100 million. The line of credit called for a commitment fee equal to 0.25% per annum of the unused portion of the line. We terminated the credit agreement in June 2021 and as of September 30, 2021, no amount was outstanding thereunder.

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

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

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

In May 2021, we entered into exchange agreements with certain holders of the 2025 Notes pursuant to which the holders exchanged $55.4 million in aggregate principal amount of the outstanding 2025 Notes for 19,051,270 shares of our Common Stock. Upon consummation of the Exchange, we paid the holders of the exchanged notes an aggregate of approximately
$0.6 million in accrued and unpaid interest on the exchanged notes. We recorded an $11.1 million non-cash loss related to the Exchange.

As of September 30, 2021, the total commitments under our A&R Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain were $93.1 million, of which $14.1 million was drawn as of September 30, 2021. At September 30, 2021, 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, 2021 was $17.2 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.

In November 2015, BioReference and certain of its subsidiaries entered into the Credit Agreement with CB, as lender, which was amended and restated on August 30, 2021 (the "A&R Credit Agreement"). The A&R Credit Agreement provides for a $75.0 million secured revolving credit facility and includes a $20.0 million sub-facility for swingline loans and a $20.0 million sub-facility for the issuance of letters of credit. The A&R Credit Agreement matures on August 30, 2024 and is

guaranteed by all of BioReference's domestic subsidiaries, subject to certain exceptions. The A&R Credit Agreement is also secured by substantially all assets of BioReference and its domestic subsidiaries, subject to certain exceptions, as well as a non-recourse pledge by us of our equity interest in BioReference. Availability under the A&R Credit Agreement is based on a borrowing base composed of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein. As of September 30, 2021, $64.3 million remained available for borrowing under the A&R Credit Agreement.

In February 2018, we issued the 2023 Convertible Notes in the aggregate principal amount of $55.0 million maturing in February 2023. Each holder of a 2023 Convertible Note has the option, from time to time, to convert all or any portion of the outstanding principal balance of such 2023 Convertible Note, together with accrued and unpaid interest thereon, into shares of our Common Stock at a conversion price of $5.00 per share. We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon upon no fewer than 30 days, and no more than 60 days, notice to the holders. The 2023 Convertible Notes contain customary events of default and representations and warranties of OPKO.

On September 14, 2021, we and LeaderMed, a pharmaceutical development company with operations based in Asia, 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 will grant the joint venture exclusive rights to develop, manufacture and commercialize (a) OPK88003, an oxyntomodulin analog being developed for the treatment of obesity and diabetes, and (b) Factor VIIa-CTP, a novel long-acting coagulation factor being developed to treat hemophilia, in exchange for a 47% ownership interest in the joint venture. In addition, we will receive an upfront payment of $1 million and will be reimbursed for clinical trial material and technical support it provides the joint venture.

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

On August 30, 2021, we announced the completion of enrollment in our Phase 2 trial with *Rayaldee* as a treatment for mild-to-moderate COVID-19. The U.S. trial, "A Randomized, Double-Blind Placebo-Controlled Study to Evaluate the Safety and Efficacy of Rayaldee (calcifediol) Extended-release Capsules to Treat Symptomatic Patients Infected with SARS-CoV-2 (REsCue)," was expected to enroll approximately 160 subjects, including some with stage 3 or 4 chronic kidney disease (CKD) who are at higher risk for developing more severe illness. Final enrollment reached 171 subjects and topline data are expected later this year.

On August 16, 2021, BioReference announced the acquisition of Ariosa Diagnostics, Inc. ("Ariosa"), the U.S. Ariosa centralized laboratory prenatal testing business from Roche Molecular Systems Inc. Ariosa's non invasive prenatal screening (NIPS) test, the Harmony Prenatal Test, is one of the most widely studied tests utilized in prenatal screening. The test has been performed in over 1.5 million patients. BioReference currently offers, ClariTest™ Core, which utilizes the same core technology as the Harmony Prenatal Test. The acquisition of Ariosa will complement our current NIPS offering.

On July 6, 2021, we entered into the CAMP4 Agreement, 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 Licensed Compound and the 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 Preferred Stock, which equates to approximately 9% of the outstanding shares of CAMP4, and we are eligible to receive up to $3.5 million in development milestone payments for Dravet syndrome products, and $4 million for non-Dravet syndrome products, as well as sales milestones of up to $90 million for Dravet syndrome products and up to $90 million for non-Dravet syndrome products. We may also receive double digit royalty payments on the net sales of royalty bearing products, subject to adjustment. In addition, upon achievement of certain development milestones, we will be eligible to receive additional 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.

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

termination rights for material breach and bankruptcy, CAMP4 is permitted to terminate the CAMP4 Agreement after a specified notice period.

On June 18, 2021, EirGen and Nicoya entered into the Nicoya Agreement granting Nicoya the exclusive rights for the development and commercialization of the Nicoya Product in the Nicoya Territory. Extended release calcifediol is marketed in the U.S. under the tradename *Rayaldee* by OPKO.

EirGen received an initial upfront payment of $5 million and is eligible to receive an additional $5 million upon the first to occur of (A) a certain predetermined milestone, or (B) the first anniversary of the effective date. 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 will also 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.

In May 2016, EirGen, partnered with VFMCRP through the VFMCRP Agreement for the development and commercialization of*Rayaldee* in the VFMCRP Territory. The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the product in human patients, 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 ("VFMCRP Initial Indication"). Effective May 23, 2021, we entered into an amendment to our agreement with VFMCRP for the development and commercialization of *Rayaldee*, pursuant to which the parties thereto agreed to include Japan as part of the VFMCRP Territory. Effective May 5, 2020, we entered into the VFMCRP Amendment, pursuant to which the parties agreed to exclude Mexico, South Korea, the Middle East and all of the countries of Africa from the VFMCRP Territory. In addition, the parties agreed to certain amendments to the milestone structure and to reduce minimum royalties payable.

We have received non-refundable and non-creditable payments of $55 million to date and are eligible to receive up to an additional $227 million pursuant to the terms of the VFMCRP Amendment upon the achievement of certain regulatory and sales-based milestones tied to sales and reimbursement levels. In addition, we are eligible to receive tiered royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon commencement of sales of the product.

As part of the arrangement, the companies will share responsibility for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. For the initial development plan, the companies have agreed to certain cost sharing arrangements. VFMCRP will be responsible for all other development costs that VFMCRP considers necessary to develop the product for the VFMCRP Initial Indication in the VFMCRP Territory except as otherwise provided in the VFMCRP Agreement. EirGen also granted to VFMCRP an option to acquire an exclusive license to use, import, offer for sale, sell, distribute and commercialize the product in the U.S. for treatment of SHPT in dialysis patients with stage 5 CKD and vitamin D insufficiency (the "Dialysis Indication"). Upon exercise of the Option, VFMCRP will reimburse EirGen for all of the development costs incurred by EirGen with respect to the product for the Dialysis Indication in the U.S. VFMCRP would also pay EirGen up to an additional aggregate amount of $555 million upon the achievement of certain milestones and would be obligated to pay royalties on sales of the product at percentage rates that range from the mid-teens to the mid-twenties or a minimum royalty, whichever is greater, upon commencement of sales of the product.

On September 24, 2021, we and Pfizer announced that the FDA has extended the review period for the BLA for Somatrogon, a once-weekly long-acting recombinant human growth hormone, for the treatment of GHD in pediatric patients. The PDUFA goal date has been extended by three months to January 2022, as a result of Pfizer's submission of additional data to the original BLA.

In October 2019, we and Pfizer announced that the global phase 3 trial evaluating Somatrogon (hGH-CTP) 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. In June 2020, we announced that the Japan phase 3 clinical trial met its primary and secondary objectives, and demonstrated that the efficacy and safety of Somatrogon administered weekly was comparable to GENOTROPIN® for injection administered once-daily as measured by annual height velocity after 12 months of treatment in treatment-naïve Japanese pre-pubertal children with GHD.

In 2014, Pfizer and OPKO entered into a worldwide agreement for the development and commercialization of our long-acting Somatrogon for the treatment of GHD in adults and children, as well as for the treatment of growth failure in children born small for gestational age. In May 2020, we entered into a Restated Agreement with Pfizer which was effective as of January 1, 2020, pursuant to which the parties agreed to share all costs for Manufacturing Activities, as defined in the Restated Agreement, for developing a licensed product for the three indications included in the Restated Agreement. Under the terms of the agreements with Pfizer, we received non-refundable and non-creditable upfront payments of $295 million in 2015 and are eligible to receive up to an additional $275 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize Somatrogon worldwide. In addition, we are eligible to receive initial tiered royalty payments

associated with the commercialization of Somatrogon for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of Somatrogon for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both Somatrogon and Pfizer's Genotropin®. During the first quarter of 2021, regulatory submissions in the major global markets for Somatrogan have been accepted including, the U.S., European Medicines Agency, and Ministry of Health, Labour, and Welfare in Japan for Somatrogon for the treatment of pediatric patients with GHD.

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

We believe that the cash and cash equivalents on hand at September 30, 2021, cash from operations, the cash received from the sale of one of our facilities in Waterford, Ireland to Horizon Therapeutics plc and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements, and the timing of those requirements, will depend on a number of factors, including the impact of the COVID-19 pandemic on our business, the approval and success of our products in development, particularly our long acting Somatrogon for which we have submitted for approval in the U.S., Europe and Japan, the commercial success of *Rayaldee*, including the launch of *Rayaldee* by Vifor expected in 2022, BioReference's financial performance, possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, our success in developing markets for our product candidates and results of government investigations, payor claims, and legal proceedings that may arise, including, without limitation class action and derivative litigation to which we are subject, and our ability to obtain insurance coverage for such claims. We have historically not generated sustained positive cash flow and if we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions or reduce our marketing or sales efforts or cease operations.

Additionally, the rapid development and fluidity of the COVID-19 pandemic and new variants of the virus makes it very difficult to predict its ultimate impact on our business, results of operations and liquidity. The pandemic presents a significant uncertainty that could materially and adversely affect our results of operations, financial condition and cash flows, including a negative impact on non-COVID-related diagnostics testing services provided by BioReference in our diagnostics segment, notwithstanding that our results of operations have been positively impacted by our provision of COVID-19 testing services. Further, deteriorating economic conditions globally as a result of the COVID-19 pandemic have in the past resulted, and may in the future result. in a challenging capital raising environment, which could materially limit our access to capital, whether through the issuance and sale of our Common Stock, debt securities or otherwise, as well as through bank facilities and lines of credit. Events resulting from the effects of COVID-19 or new variants of the virus could negatively impact our ability to comply with certain covenants in the A&R Credit Agreement or require that we pursue alternative financing. We can provide no assurance that any such alternative financing, if required, could be obtained on acceptable terms or at all. The combination of potential disruptions to our business resulting from COVID-19 together with and volatile credit and capital markets could adversely impact our future liquidity, which could have an adverse effect on our business and results of operations. We will continue to monitor and assess the impact COVID-19 and new variants of the virus may have on our business and financial results.

The following table provides information as of September 30, 2021, 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, 2021	2022	2023	2024	2025	Thereafter	Total
Open purchase orders	$ 221,546	$ 2,167	$ —	$ —	$ —	$ —	$ 223,713
Operating leases	1,450	10,789	7,239	4,954	2,993	10,654	38,079
Finance leases	564	1,579	1,020	704	239	5	4,111
2033 Senior Notes, 2025 and 2023 Convertible Notes	—	—	67,882	—	117,661	—	185,543
Deferred payments	3,750	903	—	—	—	—	4,653
Mortgages and other debts payable	275	991	795	705	235	188	3,189
Lines of credit	14,064	—	—	—	—	—	14,064
Interest commitments	2,406	9,389	6,968	6,535	573	—	25,871
Total	$ 244,055	$ 25,818	$ 83,904	$ 12,898	$ 121,701	$ 10,847	$ 499,223

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 $144.1 million.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

There were no material changes to our critical accounting policies and estimates described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, that have a material impact on our Condensed Consolidated Financial Statements and related notes.

RECENT ACCOUNTING PRONOUNCEMENTS

Pending accounting pronouncements.

In August 2020, the FASB issued ASU No. 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40).” ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. The ASU is effective for public entities for fiscal years beginning after December 15, 2021, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

In the normal course of doing business, we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

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

Although we do not speculate in the foreign exchange market, we may from time to time manage exposures that arise in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. Certain firmly committed transactions may be hedged with foreign exchange forward contracts. As exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. Both the exposed transactions and the hedging contracts are translated and fair valued, respectively, at current spot rates, with gains and losses included in earnings.

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

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

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

At September 30, 2021, we had cash and cash equivalents of $148.6 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2021 was less than 1%. As of September 30, 2021, the principal outstanding balances under BioReference's A&R Credit Agreement with CB and our Chilean and Spanish lines of credit was $14.1 million in the aggregate at a weighted average interest rate of approximately 5.4%.

Our $3.0 million aggregate principal amount of our 2033 Senior Notes has a fixed interest rate of 3%, our $55.0 million aggregate principal amount of our 2023 Convertible Notes has a fixed interest rate of 5%, and our $200.0 million aggregate principal amount of the 2025 Notes has a fixed interest rate of 4.50%, and therefore are not subject to fluctuations in market interest rates.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we may invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and money market funds that invest in such debt instruments, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than three months.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, management concluded that our disclosure controls and procedures were effective as of September 30, 2021.

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, 2021 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, except as set forth below, 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, 2020. The following should be read in conjunction with the information provided in Part I, Item 3 of such Annual Report.

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

Item 1A. Risk Factors

There have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit 10.1	Amended and Restated Credit Agreement dated as of August 30, 2021 by and between BioReference Laboratories, Inc., certain of its subsidiaries and JPMorgan Chase Bank, N.A. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on September 3, 2021)
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2021.
Exhibit 31.2	Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2021.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2021.
Exhibit 32.2	Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2021.
Exhibit 101.INS	Inline XBRL Instance Document
Exhibit 101.SCH	Inline XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	inline XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Pursuant to Item 601(b)(10)(iv) of Regulation S-K, portions of this exhibit have been omitted because the Company customarily and actually treats the omitted portions as private or confidential, and such portions are not material and would likely cause competitive harm to the Company if publicly disclosed. 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: October 28, 2021

OPKO Health, Inc.

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

Exhibit 31.1

CERTIFICATIONS

I, Phillip Frost, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: October 28, 2021

/s/ Phillip Frost, M.D.
Phillip Frost, M.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Adam Logal, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: October 28, 2021

/s/ Adam Logal

Adam Logal

Senior Vice President and Chief Financial Officer

Exhibit 32.1

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002, I, Phillip Frost, Chief Executive Officer of OPKO Health, Inc. (the "Company"), hereby certify that:

The Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 (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: October 28, 2021

/s/ Phillip Frost, M.D.
Phillip Frost, M.D.
Chief Executive Officer

Exhibit 32.2

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002, I, Adam Logal, Chief Financial Officer of OPKO Health, Inc. (the "Company"), hereby certify that:

The Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021 (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: October 28, 2021

/s/ Adam Logal

Adam Logal

Senior Vice President and Chief Financial Officer