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, 2019.

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 30, 2019, the registrant had 665,600,775 shares of Common Stock outstanding.

TABLE OF CONTENTS

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. 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, 2018 and this Quarterly Report on Form 10-Q, and described from time to time in our other filings with the Securities and Exchange Commission ("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 and could cause our actual results to differ materially from any future results expressed or implied in forward-looking statements include the following:

- we have 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 investigations, including, without limitation, recent lawsuits against the Company and its Chairman and Chief Executive Officer by the SEC, as well as related class action and derivative lawsuits;
- 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;
- the success of our relationship with Pfizer;
- that we may fail to obtain regulatory approval for hGH-CTP or successfully commercialize *Rayaldee* and hGH-CTP;
- that we may not generate profits or cash flow from our laboratory operations or substantial revenue from *Rayaldee* and our pharmaceutical and diagnostic products;
- availability of insurance coverage with respect to material litigation matters;
- 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 to build a successful pharmaceutical sales and marketing infrastructure;
- 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;
- our success is dependent on the involvement and continued efforts of our Chairman and Chief Executive Officer;
- integration challenges for acquired businesses;
- 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 Blues 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 the *4Kscore* test;
- failure to timely or accurately bill and collect for our services;
- failure in our information technology systems or those of our third party vendors, including cybersecurity attacks or other data security or privacy incidents;
- 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 wholly-owned 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, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 64,667	$ 96,473
Accounts receivable, net	140,765	143,907
Inventory, net	50,109	42,299
Other current assets and prepaid expenses	37,301	35,052
Total current assets	292,842	317,731
Property, plant and equipment, net	128,519	144,674
Intangible assets, net	564,310	614,452
In-process research and development	635,000	635,572
Goodwill	695,798	700,193
Investments	11,695	31,228
Operating lease right-of-use assets	35,826	—
Other assets	5,528	7,222
Total assets	$ 2,369,518	$ 2,451,072
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 77,296	$ 47,395
Accrued expenses	172,734	203,513
Current maturities of operating leases	12,921	—
Current portion of convertible notes	—	31,562
Current portion of lines of credit and notes payable	7,187	5,851
Total current liabilities	270,138	288,321
Operating lease liabilities	23,318	—
Convertible notes	208,695	57,299
Deferred tax liabilities, net	113,479	115,193
Other long-term liabilities, principally contract liabilities, contingent consideration and line of credit	111,959	198,968
Total long-term liabilities	457,451	371,460
Total liabilities	727,589	659,781
Equity:		
Common Stock - $0.01 par value, 1,000,000,000 and 750,000,000 shares authorized at September 30, 2019 and December 31, 2018, respectively; 616,150,952 and 586,881,720 shares issued at September 30, 2019 and December 31, 2018, respectively	6,162	5,869
Treasury Stock - 549,907 and 549,907 shares at September 30, 2019 and December 31, 2018, respectively	(1,791)	(1,791)
Additional paid-in capital	3,065,059	3,004,422
Accumulated other comprehensive loss	(28,774)	(20,131)
Accumulated deficit	(1,398,727)	(1,197,078)
Total shareholders' equity	1,641,929	1,791,291
Total liabilities and equity	$ 2,369,518	$ 2,451,072

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,	
	2019	2018	2019	2018
Revenues:				
Revenue from services	$ 181,139	$ 202,811	$ 538,488	$ 630,180
Revenue from products	26,161	25,395	80,143	81,769
Revenue from transfer of intellectual property and other	21,472	21,609	58,961	56,463
Total revenues	228,772	249,815	677,592	768,412
Costs and expenses:				
Cost of service revenue	126,348	137,347	386,329	411,196
Cost of product revenue	15,573	13,609	43,874	43,909
Selling, general and administrative	80,542	84,071	264,175	263,242
Research and development	30,017	30,160	94,832	92,258
Contingent consideration	(1,109)	1,193	(78)	(12,406)
Amortization of intangible assets	16,412	16,899	49,393	51,397
Asset impairment charges	—	—	655	—
Total costs and expenses	267,783	283,279	839,180	849,596
Operating loss	(39,011)	(33,464)	(161,588)	(81,184)
Other income and (expense), net:				
Interest income	350	43	1,477	111
Interest expense	(5,792)	(2,944)	(16,048)	(7,933)
Fair value changes of derivative instruments, net	(21)	(155)	6	3,489
Other income (expense), net	(15,470)	(824)	(20,367)	9,653
Other income and (expense), net	(20,933)	(3,880)	(34,932)	5,320
Loss before income taxes and investment losses	(59,944)	(37,344)	(196,520)	(75,864)
Income tax benefit (provision)	(1,769)	11,563	(3,636)	10,437
Net loss before investment losses	(61,713)	(25,781)	(200,156)	(65,427)
Loss from investments in investees	(294)	(1,874)	(2,419)	(11,542)
Net loss	$ (62,007)	$ (27,655)	$ (202,575)	$ (76,969)
Loss per share, basic and diluted:				
Loss per share	$ (0.11)	$ (0.05)	$ (0.35)	$ (0.14)
Weighted average common shares outstanding, basic and diluted	586,351,045	559,786,382	586,348,791	559,601,097

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

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Net loss	$ (62,007)	$ (27,655)	$ (202,575)	$ (76,969)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss)	(8,423)	(134)	(8,643)	(7,734)
Investments:				
Reclassification adjustment due to adoption of ASU 2016-01	—	—	—	(4,876)
Comprehensive loss	$ (70,430)	$ (27,789)	$ (211,218)	$ (89,579)

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 and per share data)
For the three and nine months ended September 30, 2019

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at June 30, 2019	616,150,952	$ 6,162	(549,907)	$ (1,791)	$ 3,061,631	$ (20,351)	$ (1,336,720)	$ 1,708,931
Equity-based compensation expense	—	—	—	—	3,428	—	—	3,428
Exercise of Common Stock options and warrants	—	—	—	—	—	—	—	—
Adoption of ASU 2018-07	—	—	—	—	—	—	—	—
2025 convertible notes including share lending arrangement	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(62,007)	(62,007)
Other comprehensive loss	—	—	—	—	—	(8,423)	—	(8,423)
Balance at September 30, 2019	616,150,952	$ 6,162	(549,907)	$ (1,791)	$ 3,065,059	$ (28,774)	$ (1,398,727)	$ 1,641,929

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2018	586,881,720	$ 5,869	(549,907)	$ (1,791)	$ 3,004,422	$ (20,131)	$ (1,197,078)	$ 1,791,291
Equity-based compensation expense	—	—	—	—	11,007	—	—	11,007
Exercise of Common Stock options and warrants	19,232	—	—	—	(3)	—	—	(3)
Adoption of ASU 2018-07	—	—	—	—	(926)	—	926	—
2025 convertible notes including share lending arrangement	29,250,000	293	—	—	50,559	—	—	50,852
Net loss	—	—	—	—	—	—	(202,575)	(202,575)
Other comprehensive loss	—	—	—	—	—	(8,643)	—	(8,643)
Balance at September 30, 2019	616,150,952	$ 6,162	(549,907)	$ (1,791)	$ 3,065,059	$ (28,774)	$ (1,398,727)	$ 1,641,929

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 and per share data)
For the three and nine months ended September 30, 2018

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at June 30, 2018	560,169,422	$ 5,602	(549,907)	$ (1,791)	$ 2,901,086	$ (13,004)	$ (1,093,353)	$ 1,798,540
Equity-based compensation expense	—	—	—	—	5,077	—	—	5,077
Exercise of Common Stock options and warrants	208,000	2	—	—	854	—	—	856
Adoption of ASU 2016-01	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	(27,655)	(27,655)
Other comprehensive loss	—	—	—	—	—	(134)	—	(134)
Balance at September 30, 2018	560,377,422	$ 5,604	(549,907)	$ (1,791)	$ 2,907,017	$ (13,138)	$ (1,121,008)	$ 1,776,684

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2017	560,023,745	$ 5,600	(549,907)	$ (1,791)	$ 2,889,256	$ (528)	$ (1,048,914)	$ 1,843,623
Equity-based compensation expense	—	—	—	—	16,591	—	—	16,591
Exercise of Common Stock options and warrants	353,677	4	—	—	1,170	—	—	1,174
Adoption of ASU 2016-01	—	—	—	—	—	(4,876)	4,876	—
Net loss	—	—	—	—	—	—	(76,969)	(76,969)
Other comprehensive loss	—	—	—	—	—	(7,734)	—	(7,734)
Balance at September 30, 2018	560,377,422	$ 5,604	(549,907)	$ (1,791)	$ 2,907,017	$ (13,138)	$ (1,121,007)	$ 1,776,685

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,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (202,575)	$ (76,969)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	71,281	73,440
Non-cash interest	4,558	3,559
Amortization of deferred financing costs	506	155
Losses from investments in investees	2,419	11,542
Equity-based compensation – employees and non-employees	11,007	16,591
Realized loss (gain) on disposal of fixed assets and sales of equity securities	1,455	34
Change in fair value of equity securities and derivative instruments	17,178	(14,346)
Change in fair value of contingent consideration	(78)	(12,406)
Impairment of assets	655	—
Deferred income tax (benefit) provision	2,065	(14,541)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	3,257	7,701
Inventory, net	(9,543)	4,057
Other current assets and prepaid expenses	(2,556)	(4,304)
Other assets	240	(4,633)
Accounts payable	30,597	(9,329)
Foreign currency measurement	147	57
Contract liabilities	(56,860)	(50,531)
Accrued expenses and other liabilities	(238)	(4,559)
Net cash used in operating activities	(126,485)	(74,482)
Cash flows from investing activities:		
Investments in investees	(1,200)	(1,000)
Proceeds from sale of equity securities	—	1,516
Proceeds from the sale of property, plant and equipment	552	1,070
Capital expenditures	(8,866)	(24,823)
Net cash used in investing activities	(9,514)	(23,237)
Cash flows from financing activities:		
Issuance of convertible notes, including to related parties	200,293	55,000
Debt issuance costs	(7,762)	—
Proceeds from the exercise of Common Stock options and warrants	(3)	1,173
Borrowings on lines of credit	99,353	22,468
Repayments of lines of credit	(158,477)	(28,435)
Redemption of 2033 Senior Notes	(28,800)	—
Net cash provided by financing activities	104,604	50,206
Effect of exchange rate changes on cash and cash equivalents	(411)	(268)
Net increase (decrease) in cash and cash equivalents	(31,806)	(47,781)
Cash and cash equivalents at beginning of period	96,473	91,499
Cash and cash equivalents at end of period	$ 64,667	$ 43,718
SUPPLEMENTAL INFORMATION:		
Interest paid	$ 11,084	$ 1,631
Income taxes paid, net of refunds	$ 3,103	$ 3,883
Operating lease right-of-use assets due to adoption of ASU No. 2016-02	$ 35,826	$ —
Operating lease liabilities due to adoption of ASU No. 2016-02	$ 36,239	$ —
Non-cash financing:		
Shares issued upon the conversion of:		
Common Stock options and warrants, surrendered in net exercise	$ 20	$ 806

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 focused on driving growth and leveraging new products, including the *4Kscore* prostate cancer test. Our pharmaceutical business features *Rayaldee*, an FDA-approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency (launched in November 2016); OPK88004, a selective androgen receptor modulator which we are exploring for various potential indications; and OPK88003, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists (phase 2b). Our pharmaceutical business also features hGH-CTP, a once-weekly human growth hormone that recently completed a phase 3 trial partnered with Pfizer Inc. ("Pfizer"). 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 across New York, New Jersey, Maryland, Pennsylvania, Delaware, Washington, DC, Florida, California, Texas, 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 currently generate revenue and which we expect to 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 molecular diagnostic and therapeutic products.

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

NOTE 2 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, 2019 are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2019 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, 2018.

Principles of consolidation. The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of OPKO Health, Inc. and of 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 is used in our testing laboratories. Inventory obsolescence expense for the nine months ended September 30, 2019 and 2018 was $1.4 million and $1.5 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 U.S. FDA approval. The accumulation of such pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever. This risk notwithstanding, we may accumulate pre-launch inventories of certain products when such action is appropriate in relation to the commercial value of the product launch opportunity. In accordance with our policy, this pre-launch inventory is expensed.

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 4. Goodwill, in-process research and development ("IPR&D") and other intangible assets acquired in business combinations, licensing and other transactions at September 30, 2019 and December 31, 2018 was $1.9 billion and $2.0 billion, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. We determined the fair value of intangible assets, including IPR&D, using the "income method."

Goodwill is tested annually for impairment and additionally if events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value.

Estimating the fair value of a reporting unit for goodwill impairment is highly sensitive to changes in projections and assumptions; therefore, in some instances, changes in these 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.

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 actual results are not consistent with our estimates and

assumptions, then we may be exposed to an impairment charge, which could be material. For the nine month period ending September 30, 2019, the results of operations of our BioReference reporting unit were below management's long-term forecast of expected cash flows for the year ending December 31, 2019 due to a change in reimbursement coverage for our *4Kscore* test and other market factors. If we are unable to obtain appropriate reimbursement for our *4Kscore* test and experience sustained declines in operating results versus forecast, then our estimates of the fair value of the BioReference reporting unit may change. If the fair value of the reporting unit falls below carrying value, then we would record impairment of goodwill at BioReference and such impairment could be significant.

Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the project is completed or abandoned. Upon obtaining regulatory approval, the IPR&D asset is 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.

The cost and duration of the development project for hGH-CTP have exceeded our original estimates and will result in additional expenses beyond our estimates and the development cap agreed between us and Pfizer. If we are unable to reach an agreement with Pfizer regarding cost sharing for overruns, as well as other obligations, including development obligations, it could have a material adverse impact on the expected benefits of our arrangement with Pfizer. If we are unable to successfully develop or obtain regulatory approval for hGH-CTP, or if changes in projections and assumptions negatively impact our forecast of net cash flows, then we may be exposed to a material impairment charge related to the IPR&D for hGH-CTP.

Impairment analysis and measurement is a process that requires significant judgment. Our stock price and any estimated control premium are significant qualitative factors affecting the assessment of fair value for purposes of performing our impairment assessment. Our stock price and public market capitalization has experienced volatility in the past and during 2019, our public market capitalization decreased to a value below the net book carrying value of our equity. In October 2019, our stock price also experienced a substantial decline. A significant sustained decline in our stock price and market capitalization can be a positive indicator of impairment. While no impairment was recorded as a result of the interim impairment evaluation, it is possible that a material change could occur in the future.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense was $49.4 million and $51.4 million for the nine months ended September 30, 2019 and 2018, 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, 2019 and December 31, 2018 are predominately carried at fair value. Our debt under our credit agreement with JPMorgan Chase Bank, N.A. approximates fair value due to the variable rate of interest.

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 8.

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, 2019 and December 31, 2018, our foreign currency forward contracts held to economically hedge inventory purchases did not meet the

documentation requirements to be designated as hedges. Accordingly, we recognize all changes in the fair values of our derivatives instruments, net, in our Condensed Consolidated Statement of Operations. Refer to Note 9.

Property, plant and equipment. Property, plant and equipment are recorded at cost. 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 $21.9 million and $22.0 million for the nine months ended September 30, 2019 and 2018, 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.

Impairment of long-lived assets. Long-lived assets, such as property and equipment, 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, 2019, 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 12.

Concentration of credit risk and allowance for doubtful accounts 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, 2019 and December 31, 2018, receivable

balances (net of contractual adjustments) from Medicare and Medicaid were 10.1% and 7.4%, respectively, of our consolidated Accounts receivable, net.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At September 30, 2019 and December 31, 2018, receivables due from patients represented approximately 2.3% and 2.9%, respectively, of our consolidated Accounts receivable, net.

We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer's ability to pay. Actual results could differ from those estimates. The allowance for doubtful accounts was $1.8 million and $1.8 million at September 30, 2019 and December 31, 2018, respectively. The provision for bad debts for the nine months ended September 30, 2019 and 2018 was $0.3 million and $0.6 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. During the nine months ended September 30, 2019 and 2018, we recorded $11.0 million and $16.6 million, respectively, of equity-based compensation expense.

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

Research and development expense includes costs for in-process research and development projects acquired in asset acquisitions which have not reached technological feasibility and which have no alternative future use. For in-process research and development projects acquired in business combinations, the in-process research and development project is capitalized and evaluated for impairment until the development process has been completed. Once the development process has been completed the asset will be amortized over its remaining 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 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 14.

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 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 5.

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 5. 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 5.

Recently adopted accounting pronouncements.

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, “Leases (Topic 842),” which requires organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. ASU 2016-02, as amended and codified under Topic 842, requires new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. As required, we adopted Topic 842 on January 1, 2019 and used the modified retrospective approach for all lease arrangements at the beginning or the period of adoption. Results for reporting periods beginning January 1, 2019 are presented under Topic 842, while prior period amounts were not adjusted and continue to be reported in accordance our historic accounting under ASC 840.

For leases that commenced before the effective date of Topic 842, we elected the use of permitted practical expedients and did not reassess the following: (i) whether any expired or existing contracts contain leases; (ii) the lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. We also elected the policy of not recording leases on our Condensed Consolidated Balance Sheet when the leases have terms of 12 months or less, and we elected not to separate nonlease components from lease components and instead account for each separate lease component and the nonlease components associated with that lease component as a single lease component.

The adoption of Topic 842 resulted in the recognition of operating lease liabilities of approximately$33.7 million and operating lease right-to-use assets of approximately $33.3 million as of March 31, 2019, primarily related to operating leases for our diagnostic facilities, based on the present value of lease payments over the lease term. There was no cumulative-effect adjustment to beginning Accumulated deficit on the Condensed Consolidated Balance Sheet. The accounting for our finance leases remains substantially unchanged, as finance lease liabilities and their corresponding right-to-use assets were already recorded on the Condensed Consolidated Balance Sheet under the previous guidance. The adoption of Topic 842 did not have a significant effect on our results of operations or cash flows. Refer to Note 15 for additional disclosures required by Topic 842.

In February 2018, the FASB issued ASU No. 2018-02, "Income Statement-Reporting Comprehensive Income (Topic 220)." This standard provides an option to reclassify stranded tax effects within accumulated other comprehensive loss to retained earnings due to the U.S. federal corporate income tax rate change in the Tax Cuts and Jobs Act of 2017. This standard is effective for interim and annual reporting periods beginning after December 15, 2018. We adopted this standard effective January 1, 2019 with the election not to reclassify immaterial amounts of stranded tax effects from accumulated other comprehensive loss to retained earnings.

In June 2018, the FASB issued ASU No. 2018-07, “Compensation - Stock Compensation (Topic 718),” which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The adoption of ASU 2018-07 on January 1, 2019, did not have a significant impact on our Condensed Consolidated Financial Statements.

Pending accounting pronouncements.

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,” which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses rather than incurred losses to estimate credit losses on certain types of financial instruments, including trade receivables. This may result in the earlier recognition of allowances for losses. The ASU is effective for public entities for fiscal years beginning after December 15, 2019, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

NOTE 3 EARNINGS (LOSS) PER SHARE

Basic loss per share is computed by dividing our net 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 6) 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 6. 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 herein and as discussed in Note 6) has been considered using the "if converted" method. For periods in which their effect would be antidilutive, no effect is given to outstanding options, 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 69,072,430 and 65,778,754 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2019, 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, 2019, no Common Stock options or Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of no shares of Common Stock.

During the nine months ended September 30, 2019, an aggregate of 24,877 options and warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 19,232 shares of Common Stock. Of the 24,877 Common Stock options and Common Stock warrants exercised, 5,645 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the applicable option and warrant agreements.

During the three months ended September 30, 2018, an aggregate of 208,000 options and warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 208,000 shares of Common Stock. Of the 208,000 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 applicable option and warrant agreements.

During the nine months ended September 30, 2018, an aggregate of 540,000 options and warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 353,677 shares of Common Stock. Of the 540,000 Common Stock options and Common Stock warrants exercised, 186,323 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the applicable option and warrant agreements.

NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	September 30, 2019	December 31, 2018
Accounts receivable, net:		
Accounts receivable	$ 142,605	$ 145,665
Less: allowance for doubtful accounts	(1,840)	(1,758)
	$ 140,765	$ 143,907
Inventories, net:		
Consumable supplies	$ 23,022	$ 23,264
Finished products	22,137	15,259
Work in-process	3,239	2,473
Raw materials	4,264	4,259
Less: inventory reserve	(2,553)	(2,956)
	$ 50,109	$ 42,299
Other current assets and prepaid expenses:		
Taxes recoverable	19,705	15,708
Other receivables	194	2,368
Prepaid supplies	8,915	9,693
Prepaid insurance	5,160	3,436
Other	3,327	3,847
	$ 37,301	$ 35,052
Intangible assets, net:		
Customer relationships	$ 444,524	$ 446,296
Technologies	340,539	340,729
Trade names	49,779	50,404
Licenses	5,766	5,766
Covenants not to compete	16,314	16,322
Product registrations	7,554	7,861
Other	5,974	5,613
Less: accumulated amortization	(306,140)	(258,539)
	$ 564,310	$ 614,452
Accrued expenses:		
Contract liabilities	$ 30,951	$ 63,503
Employee benefits	34,138	45,621
Clinical trials	9,975	10,401
Contingent consideration	2,375	2,375
Finance leases short-term	2,983	3,280
Milestone payment	5,000	4,871
Professional fees	2,877	7,935
Other	84,435	65,527
	$ 172,734	$ 203,513

(In thousands)	September 30, 2019	December 31, 2018
Other long-term liabilities:		
Contract liabilities	$ 3,257	$ 27,566
Line of credit	50,644	105,198
Contingent consideration	22,084	22,162
Mortgages and other debts payable	4,091	4,654
Finance leases long-term	4,325	5,620
Other	27,558	33,768
	$ 111,959	$ 198,968

Our intangible assets and goodwill relate principally to our prior acquisitions of OPKO Renal, OPKO Biologics, EirGen Pharma Limited ("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 - 5-17 years, customer relationships - 7-20 years, product registrations - 7-10 years, covenants not to compete - 5 years, trade names - 5-10 years, other 9-10 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, 2019 were primarily due to foreign currency fluctuations between the Chilean Peso, the Euro and the Shekel against the U.S. dollar.

The following table summarizes the changes in Goodwill during the nine months ended September 30, 2019.

	2019		
(In thousands)	Balance at January 1	Foreign exchange and other	Balance at September 30th
Pharmaceuticals			
CURNA	$ 4,827	$ —	$ 4,827
EirGen	85,245	(3,933)	81,312
FineTech	—	—	—
OPKO Chile	4,614	(212)	4,402
OPKO Biologics	139,784	—	139,784
OPKO Health Europe	7,546	(348)	7,198
OPKO Renal	2,069	—	2,069
Transition Therapeutics	3,322	98	3,420
Diagnostics			
BioReference	401,821	—	401,821
OPKO Diagnostics	17,977	—	17,977
OPKO Lab	32,988	—	32,988
	$ 700,193	$ (4,395)	$ 695,798

NOTE 5 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, 2019:

(in thousands)

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	$ 1,448	$ 10,268
Variable interest entity, equity method	963	—
Equity securities	9,129	
Equity securities with no readily determinable fair value	35	
Warrants and options	120	
Total carrying value of investments	$ 11,695	

Equity method investments

Our equity method investments consist of investments in Pharmsynthez (ownership 9%), Cocrystal Pharma, Inc. ("COCP") (8%), Non-Invasive Monitoring Systems, Inc. ("NIMS") (1%), Neovasc, Inc. ("Neovasc") (4%), InCellDx, Inc. ("InCellDx") (29%), BioCardia, Inc. ("BioCardia") (5%), and Xenetic Biosciences, Inc. ("Xenetic") (5%). The total assets, liabilities, and net losses of our equity method investees as of and for the nine months ended September 30, 2019 were $184.9 million, $59.9 million, and $42.1 million, respectively. We have determined that we and/or our related parties can significantly influence the success 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 price of their respective shares of common stock and the number of shares held by us as of September 30, 2019, was $9.7 million.

Equity Securities

Our equity securities consist of investments in Phio Pharmaceuticals ("Phio") (ownership 0.2%), VBI Vaccines Inc. ("VBI") (4%), ChromaDex Corporation ("ChromaDex") (0.1%), MabVax Therapeutics Holdings, Inc. ("MabVax") (1%), and Eloxx Pharmaceuticals, Inc. ("Eloxx") (3%). 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 an observable price change can be identified. Net gains and losses on our equity securities for the nine months ended September 30, 2019 are as follows:

(in thousands)

Equity Securities	For the nine months ended September 30, 2019
Net gains and losses recognized during the period on equity securities	$ (17,184)
Less: Net gains and losses realized during the period on equity securities	—
Unrealized net gains recognized during the period on equity securities still held at the reporting date	$ (17,184)

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. We did not have significant sales activity during the nine months ended September 30, 2019 and 2018. 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 purchase47 thousand additional shares of BioCardia, 23 thousand of which were vested as of September 30, 2019, and 33 thousand, 0.7 million, 40 thousand and 22 thousand of warrants to purchase additional 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 8 and Note 9.

Investments in variable interest entities

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

We own 1,260,000 shares of Zebra Series A-2 Preferred Stock and 900,000 shares of Zebra restricted common stock (ownership29% at September 30, 2019). 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 did determine, however, that we can significantly influence the success 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 6 DEBT

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, beginning on August 15, 2019. 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 on 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 circumstances. 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 will be subject to adjustment in some events, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date of the notes or if we deliver a notice of redemption, in certain circumstances we will increase 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 notes, at our option, on or after February 15, 2022, if the last reported sale price of our Common Stock has been at least 130% of the then current conversion price for the notes for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2025 Notes.

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

In 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. As at September 30, 2019, a total of 29,250,000 shares were issued under the share lending arrangement. We will not receive any of the proceeds from the sale of the borrowed shares, but we received a one-time nominal fee of $0.3 million for the newly issued shares. Shares of our Common Stock outstanding under the share lending arrangement are excluded from the calculation of basic and diluted earnings per share. See Note 3.

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, 2019:

(In thousands)	2025 Senior Notes	Discount	Debt Issuance Cost	Total
Balance at December 31, 2018	$ —	$ —	$ —	$ —
Issuance of 4.50% convertible notes	200,000	(52,600)	(5,720)	141,680
Amortization of debt discount and debt issuance costs	—	4,131	449	4,580
Balance at September 30, 2019	$ 200,000	$ (48,469)	$ (5,271)	$ 146,260

On November 8, 2018, 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 up to $60 million. The credit agreement was terminated on or around February 20, 2019 and we repaid the $28.8 million outstanding thereunder from the proceeds of the 2025 Convertible Notes offering.

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 5 years from 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 of Common Stock. We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon, 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.

The issuance of the 2023 Convertible Notes and the issuance of the Shares, if any, upon conversion thereof was not, and will not be, respectively, registered under the Securities Act, pursuant to the exemption provided by Section 4(a)(2) thereof, and we have not agreed to register the Shares if or when such Shares are issued. Purchasers of the 2023 Convertible Notes include 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 (the "2033 Senior Notes") with qualified institutional buyers and accredited investors (collectively, the "Purchasers") in a private placement in reliance on exemptions from registration under the Securities Act. The 2033 Senior Notes were issued on January 30, 2013. The 2033 Senior Notes, which totaled $175.0 million in original principal amount, bear interest at the rate of 3.00% per year, payable semiannually on February 1 and August 1 of each year. The 2033 Senior Notes will mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change as defined in that certain Indenture, dated as of January 30, 2013, by and between the Company and Wells Fargo Bank N.A., as trustee, governing the 2033 Senior Notes (the "Indenture"), 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 of 21,539,873 shares of the Company's 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, 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 for 100% 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 defined in the indenture governing the 2033 Senior Notes.

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 $100.0 million secured revolving credit facility and includes a $20.0 million sub-facility for swingline loans and a $20.0 million sub-facility for the issuance of letters of credit. The Credit Agreement matures on November 5, 2021 and is guaranteed by all of BioReference's domestic subsidiaries. The 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 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, 2019, $15.7 million additional funds were available to be borrowed under the Credit Agreement. Principal under the Credit Agreement is due upon maturity on November 5, 2021.

At BioReference's option, borrowings under the 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 0.35% for the first 12 months and 0.50% thereafter or (ii) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) plus an applicable margin of 1.35% for the first 12 months and 1.50% thereafter. Swingline loans will bear interest at the CB floating rate plus the applicable margin. The Credit Agreement also calls for other customary fees and charges, including an unused commitment fee of 0.50% of the lending commitments.

On August 6, 2019, BioReference and certain of its subsidiaries entered into Amendment No. 9 to the Credit Agreement, which amended certain definitions in the Credit Agreement and further amended the Credit Agreement to provide that the fixed charge coverage ratio requirement set forth in the Credit Agreement would not be tested for the second quarter and would not be tested for the quarter ending September 30, 2019, subject, in the case of testing for the quarter ending September 30, 2019, to (i) there having been no event of default occurring and (ii) availability under the revolving facility exceeding 10% of the total revolving commitment, subject to certain adjustments, for at least 30 consecutive days ending on September 30, 2019. The other terms of the Credit Agreement remain unchanged.

For the quarter ended September 30, 2019, $50.6 million outstanding under the Credit Agreement was included within Other long-term liabilities.

The Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require BioReference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws and restrictions on the ability of BioReference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the Credit Agreement, notwithstanding the ability of BioReference to meet its debt service obligations. The Credit Agreement also includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Credit Agreement and execution upon the collateral securing obligations under the Credit Agreement. Substantially all the assets of BioReference and its subsidiaries are restricted from sale, transfer, lease, disposal or distributions to the Company, subject to certain exceptions. BioReference and its subsidiaries net assets as of September 30, 2019, were approximately $869.5 million, which includes goodwill of $401.8 million and intangible assets of $375.6 million.

In addition to the Credit Agreement with CB, we have line of credit agreements witheleven other financial institutions as of September 30, 2019 and December 31, 2018 in the United States, Chile and Spain. These lines of credit are used primarily as a source 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, 2019	Credit line capacity	September 30, 2019	December 31, 2018
JPMorgan Chase	4.20%	$ 100,000	$ 50,644	$ 105,198
Itau Bank	5.50%	1,810	1,027	232
Bank of Chile	6.60%	3,800	1,059	432
BICE Bank	5.50%	2,500	854	818
BBVA Bank	5.50%	3,250	11	858
Security Bank	5.50%	294	294	—
Estado Bank	5.50%	3,500	888	308
Santander Bank	5.50%	4,500	1,044	852
Scotiabank	5.00%	1,800	307	2
Banco De Sabadell	1.45%	327	—	—
Banco Bilbao Vizcaya	2.75%	327	—	—
Banco Santander	1.40%	327	—	10
Total		$ 122,435	$ 56,128	$ 108,710

At September 30, 2019 and December 31, 2018, the weighted average interest rate on our lines of credit was approximately4.4% and 4.7%, respectively.

At September 30, 2019 and December 31, 2018, we had notes payable and other debt (excluding the 2033 Senior Notes, the 2023 Convertible Notes, the 2025 Notes, the Credit Agreement and amounts outstanding under lines of credit described above) as follows:

(In thousands)	September 30, 2019	December 31, 2018
Current portion of notes payable	$ 1,903	$ 2,560
Other long-term liabilities	4,932	5,693
Total	$ 6,835	$ 8,253

The notes and other debt mature at various dates ranging from2019 through 2024 bearing variable interest rates from 1.3% up to 3.8%. The weighted average interest rate on the notes and other debt at September 30, 2019 and December 31, 2018, was 2.7% and 2.1%, respectively. The notes are partially secured by our office space in Barcelona.

NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

For the nine months ended September 30, 2019, changes in Accumulated other comprehensive income (loss), net of tax, were as follows:

(In thousands)	Foreign currency translation
Balance at December 31, 2018	$ (20,131)
Other comprehensive loss before reclassifications	(8,643)
Net other comprehensive loss	(8,643)
Balance at September 30, 2019	$ (28,774)

NOTE 8 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, 2019, we had equity securities (refer to Note 5), forward foreign currency exchange contracts for inventory purchases (refer to Note 9) 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, 2019			
(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	9,129	—	—	9,129
Common stock options/warrants	—	120	—	120
Forward contracts	—	146	—	146
Total assets	$ 9,129	$ 266	$ —	$ 9,395
Liabilities:				
Contingent consideration	—	—	24,459	24,459
Total liabilities	$ —	$ —	$ 24,459	$ 24,459

	Fair value measurements as of December 31, 2018			
(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	26,313	—	—	26,313
Common stock options/warrants	—	855	—	855
Forward contracts	—	21	—	21
Total assets	$ 26,313	$ 876	$ —	$ 27,189
Liabilities:				
Contingent consideration	—	—	24,537	24,537
Total liabilities	$ —	$ —	$ 24,537	$ 24,537

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, 2019 and December 31, 2018, 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 ofSeptember 30, 2019:

(In thousands)	September 30, 2019 Contingent consideration
Balance at December 31, 2018	$ 24,537
Change in fair value:	
Included in results of operations	(78)
Balance at September 30, 2019	$ 24,459

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. If estimated future sales were to decrease by 10%, the contingent consideration related to OPKO Renal, which represents the majority of our contingent consideration liability, would decrease by $1.2 million. As of September 30, 2019, of the $24.5 million of contingent consideration, $2.4 million is recorded in Accrued expenses and $22.1 million is recorded in Other long-term liabilities. As of December 31, 2018, of the $24.6 million of contingent consideration, $2.4 million is recorded in Accrued expenses and $22.2 million is recorded in Other long-term liabilities.

NOTE 9 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, 2019	December 31, 2018
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 120	$ 855
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.	$ 146	$ 21

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, 2019 and December 31, 2018, 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, 2019 and 2018:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	2019	2018	2019	2018
Derivative gain (loss):				
Common Stock options/warrants	$ (368)	$ (288)	$ (392)	$ 3,299
Forward contracts	347	133	398	190
Total	$ (21)	$ (155)	$ 6	$ 3,489

NOTE 10 RELATED PARTY TRANSACTIONS

On March 1, 2019, OPKO Pharmaceuticals, LLC entered into an assignment agreement with Xenetic Biosciences, Inc., as amended from time to time (the "Assignment Agreement"), pursuant to which Xenetic acquired all of OPKO Pharmaceuticals' right, title and interest in and to that certain Intellectual Property License Agreement (the "IP License Agreement"), entered into between The Scripps Research Institute (the "Institute") and OPKO Pharmaceuticals, regarding certain patents for novel CAR T platform technology and through which the Institute granted an exclusive royalty-bearing license in exchange for royalties, subject to the terms of the IP License Agreement.

Under the Assignment Agreement and the IP License Agreement, Xenetic issued to OPKO Pharmaceuticals 164,062 shares of Xenetic common stock (the "OPKO Transaction Shares"). In connection with the Assignment Agreement, OPKO Pharmaceuticals entered into a voting agreement pursuant to which OPKO Pharmaceuticals agreed, among other things, to vote its shares in Xenetic in favor of the transactions contemplated by the Assignment Agreement, and a lock-up agreement with Xenetic which restricts OPKO Pharmaceuticals' sale or transfer of any of the OPKO Transaction Shares as provided therein and as otherwise required by law. The Assignment Agreement and the obligations thereunder took effect on July 19, 2019, after Xenetic satisfied certain closing conditions, including obtaining stockholder approval and securing certain financing.

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 a director of Xenetic.

In March 2019, we paid the $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 purchases of Common Stock.

In February 2019, 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 purchases of Common Stock. We reimbursed Dr. Frost for the HSR filing fee.

On November 8, 2018, we entered into stock purchase agreements with certain investors pursuant to which we agreed to sell to such investors in private placements an aggregate of approximately 26.5 million shares of our Common Stock at a purchase price of $3.49 per share, which was the closing bid price of our Common Stock on the NASDAQ on such date, for an aggregate purchase price of $92.5 million. The investors in the private placements included an affiliate of Dr. Frost ($70 million), and Dr. Hsiao ($2 million).

On November 8, 2018, 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 $60 million. Borrowings under the line of credit bore interest at a rate of 10% per annum and could have been repaid and reborrowed at any time. The credit agreement included various customary remedies for the lender following an event of default, including the acceleration of repayment of outstanding amounts under line of credit. The line of credit would have matured on November 8, 2023. We repaid approximately $28.8 million that was borrowed in 2019 and terminated the line of credit on or around February 20, 2019.

In February 2018, we issued the 2023 Convertible Notes in the aggregate principal amount of $55.0 million. Refer to Note 6. Purchasers of the 2023 Convertible Notes included Dr. Hsiao and an affiliate of Dr. Frost.

We hold investments in Zebra (ownership 29%), Neovasc (4.0%), ChromaDex Corporation (0.1%), MabVax (1%), COCP (8%), NIMS (1%), Eloxx (3%), and BioCardia (5%). 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 5.

In February 2018, we invested an additional $1.0 million in COCP for a convertible note, which was converted into 538,544 shares of its common stock in May 2018. In April 2017, we invested an additional $1.0 million in COCP for 138,889 shares of its common stock.

In November 2017, we invested an additional $3.0 million in Neovasc for 20,547 shares of its common stock, 20,547 Series A warrants, 20,547 Series B warrants and 8,221 Series C warrants, after adjusting for a 1-for-100 reverse stock split in 2018. In April 2018, we exercised the Series B warrants in a cashless exercise and received 10,690 shares of Neovasc common stock. In the first quarter of 2019, we exercised the Series C warrants for $1.2 million and exchanged the Series A warrants and received a total of 22,660 additional shares of Neovasc common stock.

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 will 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 January 1, 2017, 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 $81 thousand per month in the first year increasing annually to $86 thousand per month in the third year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking.

Our wholly-owned subsidiary, 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, 2019, we reimbursed $0 and approximately $160 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2018, we recognized approximately $34 thousand and $174 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

NOTE 11 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, 2019, we recorded $24.5 million as contingent consideration, with $2.4 million recorded within Accrued expenses and $22.1 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

On June 3, 2019, BioReference reported that Retrieval-Masters Creditors Bureau, Inc. d/b/a American Medical Collection Agency ("AMCA"), informed the Company about a data security incident involving AMCA (the "AMCA Incident"). AMCA informed the Company that an unauthorized user had access to AMCA's system between August 1, 2018 and March 30, 2019. AMCA advised that AMCA's affected system may have included patient name, date of birth, address, phone, date of service, provider, and balance information. In addition, the affected AMCA system also included credit card information, bank account information (but no passwords or security questions) and email addresses that were provided by the consumer to AMCA. AMCA has advised BioReference that no Social Security Numbers were compromised, and BioReference provided no laboratory results or diagnostic information to AMCA. BioReference has notified patients and provided notice to the Office of Civil Rights of the AMCA Incident. To date, BioReference has been named in at least two class action lawsuits against AMCA and other defendants in connection with the AMCA Incident. In addition, the Office of Inspector General and Office for Civil Rights ("OCR") of the Department of Health and Human Services, as well as the attorney generals' offices from certain states have contacted BioReference to request additional information relating to the AMCA Incident. It is not possible at this time to estimate the amount of loss or range of loss, if any, that might result from adverse judgments, settlements, fines, penalties, or other resolution of these proceedings and investigations based on the stage of these proceedings and investigations, the absence of specific allegations as to alleged damages, the uncertainty as to the certification of a class or classes and the size of any certified class, if applicable, and/or the lack of resolution of significant factual and legal issues.

As previously disclosed, on September 7, 2018, the Securities and Exchange Commission ("SEC") filed a lawsuit in the Southern District of New York (the "SEC Complaint") against a number of individuals and entities (the "Defendants"), including the Company and its CEO and Chairman, Dr. Phillip Frost. The SEC alleged, among other things, that the Company (i) aided and abetted an illegal "pump and dump" scheme perpetrated by a number of the Defendants, and (ii) failed to file required Schedules 13D or 13G with the SEC. On December 27, 2018, the Company announced that the Company and Dr. Frost entered into settlement agreements with the SEC, which upon approval of the court would resolve the SEC Complaint against each of them. The settlement was approved by the court in January 2019. Pursuant to the settlement, and without admitting or denying any of the allegations of the Complaint, the Company is enjoined from violating Section 13(d) of the Exchange Act and paid a $100,000 penalty. Liability under Section 13(d) can be established without any showing of wrongful intent or negligence.

Following the SEC's announcement of the SEC Complaint, we have been named in several class action lawsuits, more than adozen derivative suits, and other litigation relating to the allegations in the SEC Complaint among other matters. The Company intends to vigorously defend itself against the claims.

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 believes that, from 2006 to the present, 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 believes 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 is reviewing and assessing the allegations made by the SDNY.

On October 11, 2019, GeneDx received a letter from the Centers for Medicare and Medicaid Services ("CMS"), notifying GeneDx of CMS' determination to suspend Medicare payments to GeneDx, which suspension became effective on September 27, 2019 (the "CMS Letter"). The CMS Letter specifically stated that the foregoing suspension may last for up to 180 days from the effective date and may be extended under certain circumstances. CMS advised that it suspended payments due to possible overpayments to GeneDx in connection with reimbursement claims for genetic testing services based on a diagnosis of family history of cancer, which testing CMS has alleged is not covered by Medicare under the applicable provisions of the Social Security Act on the basis that such testing is not reasonable and necessary for the diagnosis or treatment of illness or injury. Medicare reimbursement payments to GeneDx were approximately $10 million for the year ended December 31, 2018. We plan to submit a rebuttal statement to CMS requesting that the suspension be removed. The payment suspension may have a significant adverse effect on GeneDx's results of operations and financial condition, and while we plan to submit a rebuttal statement to CMS, there can be no assurance that we will be successful in this effort, that CMS will not extend the suspension or that other governmental payor programs will not suspend reimbursement or seek overpayment damages from GeneDx.

From time to time, we may receive inquiries, document requests, Civil Investigative Demands ("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.

We expect to continue to incur substantial research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that selling, general and administrative expenses will also increase as we expand our sales, marketing and administrative staff and add infrastructure, particularly as it relates to *Rayaldee.* We do not anticipate that we will generate substantial revenue from the sale of proprietary pharmaceutical products or certain of our diagnostic products for some time and we have generated only limited revenue from our pharmaceutical operations in Chile, Mexico, Israel, Spain, and Ireland, and from sale of the *4Kscore* test. If we acquire additional assets or companies, fail to generate expected cash flow from BioReference, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. 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.

At September 30, 2019, we were committed to make future purchases for inventory and other items in 2019 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating approximately $77.5 million.

NOTE 12 REVENUE RECOGNITION

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

Revenue from services

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

The following are descriptions of our payors for laboratory services:

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

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

Government Payors. Reimbursements from government payors are based on fee-for-service schedules set by governmental authorities, including traditional Medicare and Medicaid. Revenues consist of amounts billed, net of contractual allowances for differences between amounts billed and the estimated consideration we expect to receive from such payors, which considers historical denial and collection experience and the terms of our contractual arrangements. Adjustments to the allowances, based on actual receipts from the government payors, are recorded upon settlement.

Client Payors. Client payors include physicians, hospitals, employers, and other institutions for which services are performed on a wholesale basis, and are billed and recognized as revenue based on negotiated fee schedules.

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

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues 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, 2019 and 2018, revenue reductions due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $25.8 million and $23.4 million, respectively, were recognized.

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 payer 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, 2019 and December 31, 2018, we have liabilities of approximately $25.5 million and $35.9 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 andnine months ended September 30, 2019 and 2018 is as follows:

(In thousands)	Three months ended September 30, 2019	Three months ended September 30, 2018	Nine months ended September 30, 2019	Nine months ended September 30, 2018
Healthcare insurers	$ 104,020	$ 123,087	$ 315,227	$ 382,778
Government payers	28,206	37,710	87,243	115,881
Client payers	43,750	36,837	120,309	114,666
Patients	5,163	5,177	15,709	16,855
Total	$ 181,139	$ 202,811	$ 538,488	$ 630,180

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 United States 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, 2019, we recognized $7.4 million and $18.8 million, respectively, in net product revenue from sales of *Rayaldee.* For the three and nine months ended September 30, 2018, we recognized $5.8 million and $14.3 million, respectively, in net product revenue from sales of *Rayaldee.*

The following table presents an analysis of product sales allowances and accruals as contract liabilities for the three and nine months ended September 30, 2019:

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at June 30, 2019	$ 1,412	$ 3,828	$ 848	$ 6,088
Provision related to current period sales	3,902	7,110	983	11,995
Adjustment related to prior period sales	313	(3)	—	310
Credits or payments made	(3,335)	(4,622)	(277)	(8,234)
Balance at September 30, 2019	$ 2,292	$ 6,313	$ 1,554	$ 10,159

Total gross *Rayaldee* sales	$ 19,661
Provision for *Rayaldee* sales allowances and accruals as a percentage of gross *Rayaldee* sales	63%

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2018	$ 1,316	$ 2,090	$ 637	$ 4,043
Provision related to current period sales	8,922	17,009	2,363	28,294
Adjustment related to prior period sales	—	99	—	99
Credits or payments made	(7,946)	(12,885)	(1,446)	(22,277)
Balance at September 30, 2019	$ 2,292	$ 6,313	$ 1,554	$ 10,159

Total gross *Rayaldee* sales	$ 47,241
Provision for *Rayaldee* sales allowances and accruals as a percentage of gross *Rayaldee* sales	60%

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

Revenue from intellectual property

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

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

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

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

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

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

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

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

For the three and nine months ended September 30, 2019, revenue from transfer of intellectual property principally reflects $19.5 million and $55.1 million of revenue, respectively, related to the Pfizer Transaction. For the three and nine months ended September 30, 2018, revenue from transfer of intellectual property principally reflects $18.9 million and $49.9 million of revenue, respectively related to the Pfizer Transaction. Refer to Note 13. Total contract liabilities included in Accrued expenses and Other long-term liabilities was $34.2 million and $91.1 million at September 30, 2019 and December 31, 2018, respectively. The contract liability balance at September 30, 2019 relates primarily to the Pfizer Transaction.

NOTE 13 STRATEGIC ALLIANCES

Japan Tobacco Inc.

On October 12, 2017, EirGen, our wholly-owned subsidiary, and Japan Tobacco Inc. ("JT") entered into a Development and License Agreement (the "JT Agreement") granting JT the exclusive rights for the development and commercialization of *Rayaldee* in Japan (the "JT Territory"). The license grant to JT covers the therapeutic and preventative use of the product for (i) SHPT in non-dialysis and dialysis patients with CKD, (ii) rickets, and (iii) osteomalacia (the "JT Initial Indications"), as well as such additional indications as may be added to the scope of the license subject to the terms of the JT Agreement (the JT Additional Indications" and together with the JT Initial Indications, the "JT Field").

In connection with the license, OPKO received an initial upfront payment of $6 million and received another $6 million upon the initiation of OPKO's Phase 2 study for *Rayaldee* in dialysis patients in the United States in September 2018 (the "Initial Consideration"). OPKO is also eligible to receive up to an additional aggregate amount of $31 million upon the achievement of certain regulatory and development milestones by JT for *Rayaldee* in the JT Territory, and $75 million upon the achievement of certain sales based milestones by JT in the JT Territory. OPKO is also entitled to receive tiered, double digit royalty payments at percentages ranging from low double digits to mid-teens on net sales of *Rayaldee* within the JT Territory. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for *Rayaldee* in Japan and for all commercial activities pertaining to *Rayaldee* in Japan.

The JT Agreement provides for the following: (1) an exclusive license in the JT Territory in the JT Field for the development and commercialization of *Rayaldee*; and (2) at JT's option, EirGen will supply products to support the development, sale and commercialization of the products to JT in the JT Territory.

The Initial Consideration will be recognized over the performance period through 2021, when we anticipate completing the transfer of license materials specified in the JT Agreement and our performance obligation is complete. Payments received for regulatory, development and sales milestones are non-refundable. The milestones are payable if and when the associated milestone is achieved and 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 these milestones.

Vifor Fresenius Medical Care Renal Pharma Ltd

In May 2016, EirGen, our wholly-owned subsidiary, and Vifor Fresenius Medical Care Renal Pharma Ltd ("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 (excluding Mexico), (iii) Russia, (iv) China, (v) Japan, (vi) Ukraine, (vii) Belorussia, (viii) Azerbaijan, (ix) Kazakhstan, and (x) Taiwan (the "VFMCRP Territory"). 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").

Under the terms of the VFMCRP Agreement, EirGen granted to VFMCRP an exclusive license in the VFMCRP Territory in the VFMCRP Field to use certain EirGen patents and technology to make, have made, use, sell, offer for sale, and import Products and to develop, commercialize, have commercialized, and otherwise exploit the Product. EirGen received a non-refundable and non-creditable initial payment of $50 million, which was recognized in Revenue from the transfer of intellectual property and other in our Condensed Consolidated Statement of Operations in 2016. EirGen also received a $2.0 million payment triggered by the approval of *Rayaldee* in Canada for the treatment of SHPT in adults with stage 3 or 4 CKD and vitamin D insufficiency in July 2018. EirGen is also eligible to receive up to an additional $35 million in regulatory milestones ("Regulatory Milestones") and $195 million in launch and sales-based milestones ("Sales Milestones"), and will 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 the commencement of sales of the Product within the VFMCRP Territory and in the VFMCRP Field.

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 hGH-CTP (Somatrogon) 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 October 21, 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.

The Pfizer Transaction closed in January 2015. Under the terms of the Pfizer Transaction, 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 hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for pediatric GHD in

certain major markets, the royalties will transition to regional, tiered gross profit sharing for both hGH-CTP 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 are recognizing the non-refundable $295.0 million upfront payments as revenue as the research and development services are completed and had contract liabilities related to the Pfizer Transaction of $28.0 million at September 30, 2019, which were classified in Accrued expenses.

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 United States. 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.

TESARO

In November 2009, we entered into an asset purchase agreement (the "NK-1 Agreement") under which we acquired VARUBI™ (rolapitant) and other neurokinin-1 ("NK-1") assets from Merck. In December 2010, we entered into an exclusive license agreement with TESARO, in which we out-licensed the development, manufacture, commercialization and distribution of our lead NK-1 candidate, VARUBI™ (the "TESARO License"). Under the terms of the license, we received a $6.0 million upfront payment from TESARO and we received $30 million of milestone payments from TESARO upon achievement of certain regulatory and commercial sale milestones and we are eligible to receive additional commercial milestone payments of up to $85 million if specified levels of annual net sales are achieved. The sales based milestone payments will be recognized as revenue in full in the period in which the associated sales occur. During the nine months ended September 30, 2019 and 2018, no revenue was recognized related to the achievement of the milestones under the TESARO License.

Under the TESARO License, TESARO was also obligated to pay us tiered royalties on annual net sales achieved in the U.S. and Europe at percentage rates that range from the low double digits to the low twenties, and outside of the U.S. and Europe at low double-digit percentage rates until the later of the date that all of the patent rights licensed from us and covering VARUBI™ expire, are invalidated or are not enforceable and 12 years from the first commercial sale of the product. TESARO announced during the first quarter of 2018 that it has elected to suspend further distribution of Varubi IV. In June 2018, TESARO assigned its rights and obligations under the agreement to TerSera Therapeutics LLC ("TerSera") pursuant to an asset purchase agreement. Under the asset purchase agreement, TerSera is responsible for VARUBI in the United States and Canada and TESARO was permitted to continue to commercialize VARUBY® in Europe and the rest of the world though a sublicense with TerSera. In September 2019, TESARO informed us and TerSera that it intends to stop selling VARUBY® and that it plans to withdraw its marketing authorizations for the product.

The term of the remaining license with TerSera will remain in force until the expiration of the royalty term in each country, unless we terminate the license earlier for material breach of the license or bankruptcy. TerSera has a right to terminate the license at any time during the term for any reason on three months' written notice.

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.

Phio Pharmaceuticals Corp.

In March 2013, we completed the sale to RXi Pharmaceuticals Corporation (now known as Phio Pharmaceuticals Corp.) of substantially all of our assets in the field of RNA interference (the "RNAi Assets") (collectively, the "Asset Purchase Agreement"). Pursuant to the Asset Purchase Agreement, Phio will be required to pay us up to $50.0 million in milestone payments upon the successful development and commercialization of each drug developed by Phio, certain of its affiliates or any of its or their licensees or sublicensees utilizing patents included within the RNAi Assets (each, a "Qualified Drug"). In addition, Phio will also be required to pay us royalties equal to: (a) a mid single-digit percentage of "Net Sales" (as defined in the Asset Purchase Agreement) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable "Royalty Period" (as defined in the Asset Purchase Agreement); and (b) a low single-digit percentage of net sales with respect to each Qualified Drug sold for a non-ophthalmologic use during the applicable Royalty Period.

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 14 SEGMENTS

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

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

(In thousands)	For the three months ended September 30, 2019	For the three months ended September 30, 2018	For the nine months ended September 30, 2019	For the nine months ended September 30, 2018
Revenue from services:				
Pharmaceutical	$ —	$ —	$ —	$ —
Diagnostics	181,139	202,811	538,488	630,180
Corporate	—	—	—	—
	$ 181,139	$ 202,811	$ 538,488	$ 630,180
Revenue from products:				
Pharmaceutical	$ 26,161	$ 25,395	$ 80,143	$ 81,769
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ 26,161	$ 25,395	$ 80,143	$ 81,769
Revenue from transfer of intellectual property and other:				
Pharmaceutical	$ 21,472	$ 21,609	$ 58,961	$ 56,463
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$ 21,472	$ 21,609	$ 58,961	$ 56,463
Operating loss:				
Pharmaceutical	$ (14,232)	$ (16,937)	$ (52,265)	$ (37,721)
Diagnostics	(16,363)	(11,082)	(77,945)	(17,624)
Corporate	(8,416)	(5,445)	(31,378)	(25,839)
	$ (39,011)	$ (33,464)	$ (161,588)	$ (81,184)
Depreciation and amortization:				
Pharmaceutical	$ 7,673	$ 7,021	$ 22,580	$ 20,514
Diagnostics	16,116	16,880	48,647	52,855
Corporate	16	20	54	71
	$ 23,805	$ 23,921	$ 71,281	$ 73,440
Loss from investment in investees:				
Pharmaceutical	$ (294)	$ (1,603)	$ (2,419)	$ (10,715)
Diagnostics	—	(271)	—	(827)
Corporate	—	—	—	—
	$ (294)	$ (1,874)	$ (2,419)	$ (11,542)
Revenues:				
United States	$ 189,485	$ 208,646	$ 558,688	$ 646,492
Ireland	22,968	24,407	65,675	62,468
Chile	8,436	8,926	25,352	32,596
Spain	4,172	4,144	13,466	14,269
Israel	1,938	2,283	8,822	8,424
Mexico	1,642	1,382	5,231	4,105
Other	131	27	358	58
	$ 228,772	$ 249,815	$ 677,592	$ 768,412

(In thousands)	September 30, 2019	December 31, 2018
Assets:		
Pharmaceutical	$ 1,235,513	$ 1,236,499
Diagnostics	1,114,485	1,162,160
Corporate	19,520	52,413
	$ 2,369,518	$ 2,451,072
Goodwill:		
Pharmaceutical	$ 243,011	$ 247,407
Diagnostics	452,787	452,786
Corporate	—	—
	$ 695,798	$ 700,193

No customer represented more than 10% of our total consolidated revenue during the three and nine months ended September 30, 2019 and 2018. As of September 30, 2019 and December 31, 2018, no customer represented more than 10% of our accounts receivable balance.

NOTE 15 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.

The following table presents the lease balances within the Condensed Consolidated Balance Sheet as of September 30, 2019:

(in thousands)	Classification on the Balance Sheet	September 30, 2019
Assets		
Operating lease assets	Operating lease right-of-use assets	$ 35,826
Finance lease assets	Property, plant and equipment, net	7,308
Liabilities		
Current		
Operating lease liabilities	Current maturities of operating leases	12,921
Accrued expenses	Current maturities of finance leases	2,983
Long-term		
Operating lease liabilities	Operating lease liabilities	23,318
Other long-term liabilities	Finance lease liabilities	$ 4,325
Weighted average remaining lease term		
Operating leases		2.6 years
Finance leases		2.4 years
Weighted average discount rate		
Operating leases		5.7%
Finance leases		4.9%

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, 2019:

(in thousands)	Operating	Finance
October 1, 2019 through December 31, 2019	$ 3,938	$ 923
2020	11,929	2,845
2021	8,471	2,133
2022	5,700	1,077
2023	4,294	486
Thereafter	7,215	203
Total undiscounted future minimum lease payments	41,547	7,667
Less: Difference between lease payments and discounted lease liabilities	5,308	360
Total lease liabilities	$ 36,239	$ 7,307

Expense under operating leases and finance leases was $15.3 million and $2.3 million, respectively, for the nine months ended September 30, 2019, and includes $2.6 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)	Nine months ended September 30, 2019
Operating cash out flows from operating leases	$ 15,664
Operating cash out flows from finance leases	306
Financing cash out flows from finance leases	2,165
Total	$ 18,135

NOTE 16 SUBSEQUENT EVENTS

On October 21, 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.

Top-line results from the study demonstrated that treatment with Somatrogon dosed once-weekly in pre-pubertal children with GHD was non-inferior to somatropin dosed once-daily with respect to height velocity at 12 months of treatment (the primary endpoint); the least square mean was higher in the Somatrogon group (10.12 cm/year) than in the somatropin group (9.78 cm/year); the treatment difference (Somatrogon – somatropin) in height velocity (cm/year) was 0.33 with a two-sided 95% confidence interval of the difference of (-0.39, 1.05). In addition, change in height standard deviation scores at six months and twelve months, key secondary endpoints, were higher in the Somatrogon dosed once-weekly cohort in comparison to the somatropin dosed once-daily cohort. Moreover, at six months, change in height velocity, another key secondary endpoint, was higher in the Somatrogon dosed once-weekly cohort in comparison to the somatropin dosed once-daily cohort. These common measures of growth are employed in the clinical setting to measure the potential level of catch-up growth that subjects may experience relative to heights of age and gender matched peers.

Somatrogon was generally well tolerated in the study and comparable to that of somatropin dosed once-daily with respect to the types, numbers and severity of the adverse events observed between the treatment arms. Immunogenicity testing and analysis of additional data are ongoing, and full results of the study will be submitted for presentation at a future scientific meeting.

In 2014, Pfizer and OPKO entered into a worldwide agreement for the development and commercialization of Somatrogon for the treatment of GHD. Under the agreement, we are responsible for conducting the clinical program and Pfizer is responsible for registering and commercializing the product (see Note 13).

On October 29, 2019, we issued50 million shares of our Common Stock at a price of$1.50 per share in an underwritten public offering (the “Offering”), resulting in net proceeds to the Company of approximately $70 million, after deducting underwriting commissions and offering expenses. The Company also granted the underwriters an option for a period of 30 days to purchase up to an additional7.5 million shares at the public offering price, less underwriting discounts and commissions. The Company intends to use the net proceeds received from the Offering to fund research and development, to further develop and commercialize its portfolio of proprietary pharmaceutical and diagnostic products and for working capital, capital expenditures, acquisitions and other general corporate purposes. Drs. Frost and Hsiao and Mr. Steven Rubin, members of OPKO’s senior management purchased an aggregate of 2,415,000 shares in the Offering.

On November 4, 2019, BioReference and certain of its subsidiaries entered into Amendment No. 10 to the Credit Agreement, which amended certain definitions in the Credit Agreement and further amended the Credit Agreement to extend the maturity date to 2021 and reduce the commitment from $100 million to $75 million. The other terms of the Credit Agreement remain unchanged.

We have reviewed all subsequent events and transactions that occurred after the date of ourSeptember 30, 2019 Condensed Consolidated Balance Sheet date, through the time of filing this Quarterly Report on Form 10-Q.

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 and in our Annual Report on Form 10-K for the year ended December 31, 2018 (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 II, Item 1A of the Form 10-K for the year ended December 31, 2018, and in Part II, Item 1A of this Quarterly Report on Form 10-Q 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* prostate cancer test. Our pharmaceutical business features *Rayaldee*, an FDA-approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency (launched in November 2016), OPK88004, a selective androgen receptor modulator which we are exploring for various potential indications, and OPK88003, a once weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists (phase 2b). Our pharmaceutical business also features hGH-CTP, a once-weekly human growth hormone which recently completed a phase 3 study and is partnered with Pfizer.

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

RECENT DEVELOPMENTS

On November 4 2019, BioReference and certain of its subsidiaries entered into Amendment No. 10 to the Credit Agreement, which amended certain definitions in the Credit Agreement and further amended the Credit Agreement to extend the maturity date to 2021 and reduce the commitment from $100 million to $75 million. The other terms of the Credit Agreement remain unchanged.

On October 29, 2019, we issued 50 million shares of our common stock at a price to the public of $1.50 per share in an underwritten public offering (the "Offering"), resulting in net proceeds to the Company of approximately $70 million after deducting underwriting commissions and offering expenses. The Company also granted the underwriters an option for a period of 30 days to purchase up to an additional 7.5 million shares at the public offering price, less underwriting discounts and commissions.

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

Top-line results from the study demonstrated that treatment with Somatrogon dosed once-weekly in pre-pubertal children with GHD was non-inferior to somatropin dosed once-daily with respect to height velocity at 12 months of treatment (the primary endpoint); the least square mean was higher in the Somatrogon group (10.12 cm/year) than in the somatropin group (9.78 cm/year); the treatment difference (Somatrogon – somatropin) in height velocity (cm/year) was 0.33 with a two-sided 95% confidence interval of the difference of (-0.39, 1.05). In addition, change in height standard deviation scores at six and twelve months, key secondary endpoints, were higher in the Somatrogon dosed once-weekly cohort in comparison to the somatropin dosed once-daily cohort. Moreover, at six months, change in height velocity, another key secondary endpoint, was higher in the Somatrogon dosed once-weekly cohort in comparison to the somatropin dosed once-daily cohort. These common measures of growth are employed in the clinical setting to measure the potential level of catch-up growth that subjects may

experience relative to heights of age and gender matched peers. Somatrogon was generally well tolerated in the study and comparable to that of somatropin dosed once-daily with respect to the types, numbers and severity of the adverse events observed between the treatment arms. Immunogenicity testing and analysis of additional data are ongoing, and full results of the study will be submitted for presentation at a future scientific meeting.

RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018

Revenues

(In thousands)	For the three months ended September 30, 2019	2018	Change
Revenue from services	$ 181,139	$ 202,811	$ (21,672)
Revenue from products	26,161	25,395	766
Revenue from transfer of intellectual property and other	21,472	21,609	(137)
Total revenues	$ 228,772	$ 249,815	$ (21,043)

Revenue from services for the three months ended September 30, 2019 decreased approximately $21.7 million compared to the three months ended September 30, 2018. Revenue from services for the three months ended September 30, 2019 was negatively affected by decreased reimbursement from our clinical testing of $11.7 million and from our genomics testing of $1.5 million as a result of an increase in denial rates and changes to payor pricing, policy and procedural requirements and the impact of Protecting Access to Medicare Act of 2014 ("PAMA"), as well as a decline in *4Kscore* revenue due to the Novitas non-coverage determination which became effective March 21, 2019. Novitas is the Medicare Administrative Contractor ("MAC") for a jurisdiction that includes the State of New Jersey, where our *4Kscore* test samples are processed. Subsequent to the effective date of the non-coverage determination, Novitas issued a new proposed local coverage determination ("LCD") for the *4Kscore* test under which Novitas proposes reimbursing the *4Kscore* test for patients who meet certain defined criteria. The final LCD for *4Kscore* test is expected to be issued in the fourth quarter of 2019.

Revenue from services for the three months ended September 30, 2019 were also negatively affected by $4.1 million as a result of a reduction in clinical test volumes, which was partially offset by higher volume in our genomics testing of $1.8 million.

Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues 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, 2019 and 2018, revenue reductions due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $6.0 million and $10.0 million, respectively, were recognized.

The composition of Revenue from services by payor for the three months ended September 30, 2019 and 2018 is as follows:

(In thousands)	Three months ended September 30, 2019	2018
Healthcare insurers	$ 104,020	$ 123,087
Government payers	28,206	37,710
Client payers	43,750	36,837
Patients	5,163	5,177
Total	$ 181,139	$ 202,811

Overall, Revenue from products for the three months ended September 30, 2019 was consistent with the comparative period in 2018 as an increase in *Rayaldee* sales was partially offset by a decrease in revenue at OPKO Chile. The increase in *Rayaldee* sales volume was also partially offset by an increase in governmental rebates on *Rayaldee* sales in 2019 related to the Medicare Part D Coverage Gap. Revenue from transfer of intellectual property for the three months ended September 30, 2019 and 2018 principally reflected $19.5 million and $18.9 million, respectively, of revenue related to the Pfizer Transaction.

Cost of revenue. Cost of revenue for the three months ended September 30, 2019 decreased $9.0 million compared to 2018. Cost of service revenue decreased in 2019 due cost reduction initiatives resulting in per patient encounter efficiency gains at BioReference. Cost of product revenue increased primarily due to changes in the product mix of items sold during the period. Cost of revenue for the three months ended September 30, 2019 and 2018 was as follows:

Cost of Revenue	For the three months ended September 30,		
(In thousands)	2019	2018	Change
Cost of service revenue	$ 126,348	$ 137,347	$ (10,999)
Cost of product revenue	15,573	13,609	1,964
Total cost of revenue	$ 141,921	$ 150,956	$ (9,035)

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2019 and 2018 were $80.5 million and $84.1 million, respectively. The decrease in selling, general and administrative expenses was primarily due to decreased expenses at BioReference due to planned cost reduction initiatives. Selling, general and administrative expenses for the three months ended September 30, 2019 and 2018 included equity-based compensation expense of $2.4 million and $3.4 million, respectively.

Research and development expenses. Research and development expenses for the three months ended September 30, 2019 and 2018 were $30.0 million and $30.2 million, respectively. Research and development costs 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. We track external research and development expenses by individual program for Phase 3 clinical trials for drug approval and pre-market approvals ("PMAs") 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	For the three months ended September 30,	
	2019	2018
External expenses:		
Manufacturing expense for biological products	$ 12,708	$ 9,087
Phase III studies	6,862	9,889
Earlier-stage programs	1,635	6,848
Research and development employee-related expenses	3,745	3,027
Other internal research and development expenses	5,067	2,149
Third-party grants and funding from collaboration agreements	—	(840)
Total research and development expenses	$ 30,017	$ 30,160

For the three months ended September 30, 2019 and 2018, we recorded, as an offset to research and development expenses, $3.7 million and $5.2 million, respectively, related to research and development tax credits recognized in Ireland. Research and development expenses for the three months ended September 30, 2019 and 2018 included equity-based compensation expense of $0.6 million and $1.0 million, respectively. We expect our research and development expenses to increase as we continue to expand our research and development of potential future products.

Contingent consideration. Contingent consideration for the three months ended September 30, 2019 and 2018 was $1.1 million of income and $1.2 million of expense, respectively. The change in contingent consideration was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal in both periods. The contingent consideration liabilities at September 30, 2019 related to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $16.4 million and $16.9 million, respectively, for the three months ended September 30, 2019 and 2018. 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 U.S. 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.

Interest income. Interest income for the three months ended September 30, 2019 and 2018 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, 2019 and 2018 was $5.8 million and $2.9 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 its credit facility. The increase in interest expense for the three months ended September 30, 2019 was primarily due to interest incurred on the 2025 Notes and 2023 Convertible Notes.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended September 30, 2019 and 2018, was $21 thousand and $0.2 million of expense, respectively. Derivative expense for the three months ended September 30, 2019 and 2018 principally related to the change in the fair value of warrants to purchase additional shares of Xenetic.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2019 and 2018, was $15.5 million and $0.8 million of expense, respectively. Other income (expense) for the three months ended September 30, 2019 primarily consisted of net unrealized gains (losses) recognized during the period on our investments in Eloxx Pharmaceuticals, Inc. and VBI Vaccines Inc.

Income tax benefit (provision). Our income tax benefit (provision) for the three months ended September 30, 2019 and 2018 was $(1.8) million and $11.6 million, respectively, and reflects quarterly results using our expected effective tax rate. For the three months ended September 30, 2019, 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. The income tax benefit for the three months ended September 30, 2018 included benefits related to discrete events which did not recur during 2019.

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 $0.3 million and $1.9 million for the three months ended September 30, 2019 and 2018, respectively.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018

Revenues	For the nine months ended September 30,		
(In thousands)	2019	2018	Change
Revenue from services	$ 538,488	$ 630,180	$ (91,692)
Revenue from products	80,143	81,769	(1,626)
Revenue from transfer of intellectual property and other	58,961	56,463	2,498
Total revenues	$ 677,592	$ 768,412	$ (90,820)

Revenue from services for the nine months ended September 30, 2019 decreased approximately $91.7 million compared to the nine months ended September 30, 2018. Revenue from services for the nine months ended September 30, 2019 was negatively affected by decreased reimbursement from our clinical testing of $45.6 million and from our genomics testing of $23.5 million, as a result of an increase in denial rates and changes to payor pricing, policy and procedural requirements and the impact of PAMA, as well as a decline in *4Kscore* revenue due to the non-coverage decision issued by Novitas which became effective on March 21, 2019. Subsequent to the effective date of the non-coverage determination, Novitas issued a new proposed LCD for the *4Kscore* test under which Novitas proposes reimbursing the *4Kscore* test for patients who meet certain defined criteria. The final LCD for *4Kscore* test is expected to be issued in the fourth quarter of 2019.

Revenue from services for the nine months ended September 30, 2019 were also negatively affected by $8.7 million as a result of a reduction in clinical test volumes, which was offset by higher volume in our genomics testing of $12.3 million.

Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as issues 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, 2019 and 2018, revenue reductions due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of $25.8 million and $23.4 million, respectively, were recognized.

The composition of Revenue from services by payor for thenine months ended September 30, 2019 and 2018 was as follows:

	For the nine months ended September 30,	
(In thousands)	2019	2018
Healthcare insurers	$ 315,227	$ 382,778
Government payers	87,243	115,881
Client payers	120,309	114,666
Patients	15,709	16,855
Total	$ 538,488	$ 630,180

The decrease in Revenue from products was primarily attributable to a decrease in revenue at OPKO Chile due to the lack of availability of certain products, which was partially offset by an increase in sales of *Rayaldee*. Revenue from transfer of intellectual property for the nine months ended September 30, 2019 and 2018 principally reflected $55.1 million and $49.9 million, respectively, of revenue related to the Pfizer Transaction.

Cost of revenue. Cost of revenue for the nine months ended September 30, 2019 decreased $24.9 million compared to 2018. Cost of service revenue decreased in 2019 due to cost reduction initiatives resulting in per patient encounter efficiency gains at BioReference. The change in cost of product revenue was attributable to changes in the product mix of items sold during the period. Cost of revenue for the nine months ended September 30, 2019 and 2018 was as follows:

Cost of Revenue	For the nine months ended September 30,		
(In thousands)	2019	2018	Change
Cost of service revenue	$ 386,329	$ 411,196	$ (24,867)
Cost of product revenue	43,874	43,909	(35)
Total cost of revenue	$ 430,203	$ 455,105	$ (24,902)

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2019 and 2018 were $264.2 million and $263.2 million, respectively. The increase in selling, general and administrative expenses was primarily due to $12.6 million of expenses incurred in connection with certain legal matters, which was partially offset by decreased expenses at BioReference due to planned cost reduction initiatives. Selling, general and administrative expenses for the nine months ended September 30, 2019 and 2018 included equity-based compensation expense of $8.0 million and $11.2 million, respectively.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2019 and 2018 were $94.8 million and $92.3 million, respectively. Research and development costs 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. We track external research and development expenses by individual program for Phase 3 clinical trials for drug approval and pre-market approvals (“PMAs”) 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	For the nine months ended September 30,	
	2019	2018
External expenses:		
Manufacturing expense for biological products	$ 32,819	$ 21,028
Phase III studies	17,256	22,149
Earlier-stage programs	5,074	14,245
Research and development employee-related expenses	18,299	19,683
Other internal research and development expenses	21,761	15,993
Third-party grants and funding from collaboration agreements	(377)	(840)
Total research and development expenses	$ 94,832	$ 92,258

The increase in research and development expenses for the 2019 period was primarily due to an increase in research and development expenses related to hGH-CTP, a long acting human growth hormone that was outlicensed to Pfizer in 2015. In addition, for the nine months ended September 30, 2019 and 2018, we recorded, as an offset to research and development expenses, $3.7 million and $5.2 million, respectively, related to research and development tax credits recognized in Ireland. Research and development expenses for the nine months ended September 30, 2019 and 2018 included equity-based compensation expense of $1.5 million and $3.3 million, respectively. We expect our research and development expenses to increase as we continue to expand our research and development of potential future products.

Contingent consideration. Contingent consideration income (expense) for the nine months ended September 30, 2019 and 2018 was $78 thousand and $12.4 million , respectively. The change in contingent consideration was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal and OPKO Diagnostics. The contingent consideration liabilities at September 30, 2019 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $49.4 million and $51.4 million, respectively, for the nine months ended September 30, 2019 and 2018. 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 U.S. 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.

Asset impairment charges. Asset impairment charges were $0.7 million for the nine months ended September 30, 2019 and is related to an impairment charge to write down our intangible assets at FineTech down to their estimated fair value.

We believe that our estimates and assumptions in testing goodwill and other intangible assets, including IPR&D, for impairment are consistent with assumptions that marketplace participants would use in their estimates. However, if actual results are not consistent with our estimates and assumptions, we may be exposed to an impairment charge that could be material.

If we are unable to obtain appropriate reimbursement for our *4Kscore* test and experience sustained declines in operating results at BioReference versus management's forecast, then our estimates of the fair value of the BioReference reporting unit may change. If the fair value of the reporting unit falls below carrying value, then we would record impairment of goodwill at BioReference and such impairment could be significant.

The development project for hGH-CTP has exceeded our original estimates and will result in additional expenses beyond our estimates and the agreed development cap. If we are unable to reach an agreement with Pfizer regarding cost sharing for overruns, as well as other obligations, including development obligations, it could have a material adverse impact on the expected benefits of the Pfizer transaction. If we are unable to successfully develop hGH-CTP, or changes in projections and assumptions negatively impact our forecast of net cash flows, we may be exposed to a material impairment charge related to the IPR&D for hGH-CTP.

Interest income. Interest income for the nine months ended September 30, 2019 and 2018 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, 2019 and 2018 was $16.0 million and $7.9 million, respectively. Interest expense is principally related to interest incurred on the 2025 Notes, the 2023 Convertible Notes, the 2033 Senior Notes, and BioReference's outstanding debt under its credit facility. The increase in interest expense for the nine months ended September 30, 2019 was primarily due to interest incurred on the 2025 Notes and 2023 Convertible Notes.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the nine months ended September 30, 2019 and 2018, was $6 thousand and $3.5 million of income, respectively. Derivative income for the nine months ended September 30, 2018 principally related to the change in the fair value of warrants to purchase additional shares of Neovasc, Inc.

Other income (expense), net. Other income (expense), net for the nine months ended September 30, 2019 and 2018, was $20.4 million of expense and $9.7 million of income, respectively. Other expense for the nine months ended September 30, 2019 primarily consisted of net unrealized losses recognized during the period on our investments in Eloxx Pharmaceuticals, Inc. and VBI Vaccines Inc. Other income for the nine months ended September 30, 2018 primarily consists of net unrealized gains recognized during the period on equity securities.

Income tax benefit (provision). Our income tax benefit (provision) for the nine months ended September 30, 2019 and 2018 was $(3.6) million and $10.4 million, respectively, and reflects quarterly results using our expected effective tax rate. For the nine months ended September 30, 2019, 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. The income tax benefit for the nine months ended September 30, 2018 included benefits related to discrete events which did not recur during 2019.

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 a net loss. Loss from investments in investees was $2.4 million and $11.5 million for the nine months ended September 30, 2019 and 2018, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2019, we had cash and cash equivalents of approximately $64.7 million. Cash used in operations of $126.5 million for the nine months ended September 30, 2019 principally reflects general and administrative expenses in connection with our corporate operations, research and development activities and commercialization activities related to *Rayaldee.* Cash used in investing activities for the nine months ended September 30, 2019 primarily reflects capital expenditures of $8.9 million. Cash provided by financing activities primarily reflects the issuance of the 2025 Notes in February 2019 for net proceeds of $192.5 million, which was partially offset by the redemption of $28.8 million principal amount of 2033 Senior Notes and repayments on BioReference's line of credit with JPMorgan Chase Bank, N.A. ("CB"). We have not generated sustained positive cash flow sufficient to offset our operating and other expenses and our primary source of cash has been from the public and private placement of stock, the issuance of the 2033 Senior Notes, 2023 Convertible Notes and 2025 Notes and credit facilities available to us.

On October 29, 2019, we issued 50 million shares of our common stock at a price to the public of $1.50 per share in an underwritten public offering (the "Offering"), resulting in net proceeds to the Company of approximately $70 million, after deducting underwriting commissions and offering expenses. The Company also granted the underwriters an option for a period of 30 days to purchase up to an additional 7.5 million shares at the public offering price, less underwriting discounts and commissions. The Company intends to use the net proceeds received from the Offering to fund research and development, to further develop and commercialize its portfolio of proprietary pharmaceutical and diagnostic products and for working capital, capital expenditures, acquisitions and other general corporate purposes.

In February 2019, we issued $200.0 million aggregate principal amount of the 2025 Notes in an underwritten public offering. The 2025 Notes bear interest at a rate of 4.50% per year, payable semiannually in arrears on February 15 and August 15 of each year, beginning on August 15, 2019. 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 on 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 circumstances. 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 some events but will not be adjusted for any accrued and unpaid interest.

On November 8, 2018, we entered into stock purchase agreements with certain investors pursuant to which we agreed to sell to such investors in private placements an aggregate of approximately 26.5 million shares of our Common Stock at a purchase price of $3.49 per share, which was the closing bid price of our Common Stock on the NASDAQ on such date, for an aggregate purchase price of $92.5 million. The investors in the private placements included an affiliate of Dr. Phillip Frost, our Chairman and Chief Executive Officer ($70 million), and Dr. Jane Hsiao, our Vice Chairman and Chief Technical Officer ($2 million). We intend to use the proceeds from the private placements for general corporate purposes.

On November 8, 2018, 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 up to $60 million. The credit agreement was terminated on or around February 20, 2019 and we repaid the $28.8 million outstanding from the proceeds of the 2025 Notes offering. Borrowings under the line of credit bore interest at a rate of 10% per annum and could be repaid and reborrowed at any time. The credit agreement included various customary remedies for the lender following an event of default, including the acceleration of repayment of outstanding amounts under line of credit. The line of credit would have matured on November 8, 2023.

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, following which repurchase only $3.0 million aggregate principal amount of the 2033 Senior Notes remained outstanding. At December 31, 2018, $31.9 million principal amount of 2033 Senior Notes was outstanding. Holders of the remaining $3.0 million principal amount of the 2033 Senior Notes may require us to repurchase such notes for 100% 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 defined in the indenture governing the 2033 Senior Notes.

As of September 30, 2019, the total commitments under our Credit Agreement (as defined below) with CB and our lines of credit with financial institutions in Chile and Spain was $88.8 million, of which $56.1 million was used and outstanding as of September 30, 2019. The weighted average interest rate on these lines of credit was approximately 4.4%. These lines of credit are short-term and are used primarily as a source of working capital. The highest balance at any time during the nine months ended September 30, 2019 was $112.4 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that our current lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

In the second quarter of 2019, we repaid$39.0 million under our Credit Agreement with CB based on changes in our borrowing base calculation which reduced credit available to us. The repayment was made with cash on hand. As of September 30, 2019, $15.7 million remained available for borrowing under the Credit Agreement.

On August 6, 2019, BioReference and certain of its subsidiaries entered into Amendment No. 9 to the Credit Agreement, which amended certain definitions in the Credit Agreement and further amended the Credit Agreement to provide that the fixed charge coverage ratio requirement set forth in the Credit Agreement would not be tested for the second quarter and would not be tested for the quarter ending September 30, 2019, subject, in the case of testing for the quarter ending September 30, 2019, to (i) there having been no event of default occurring and (ii) availability under the revolving facility exceeding 10% of the total revolving commitment, subject to certain adjustments, for at least 30 consecutive days ending on September 30, 2019. The other terms of the Credit Agreement remain unchanged.

On November 4, 2019, BioReference and certain of its subsidiaries entered into Amendment No. 10 to the Credit Agreement, which amended certain definitions in the Credit Agreement and further amended the Credit Agreement to extend the maturity date to 2021 and reduce the commitment from $100 million to $75 million. The other terms of the Credit Agreement remain unchanged.

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. The Credit Agreement matures on November 5, 2021 and is guaranteed by all of BioReference's domestic subsidiaries. The 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 Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of BioReference and certain of its subsidiaries, as specified therein.

In February 2018, we issued the 2023 Convertible Notes in the aggregate principal amount of $55.0 million. The 2023 Convertible Notes mature five years from 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, par value $0.01 per share, at a conversion price of $5.00 per share of common stock. We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon, pro ratably 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.

The issuance of the 2023 Convertible Notes and the issuance of the Shares, if any, upon conversion thereof was not, and will not be, respectively, registered under the Securities Act, pursuant to the exemption provided by Section 4(a)(2) thereof, and we have not agreed to register the shares of common stock issuable upon conversion if or when such shares are issued. Purchasers of the 2023 Convertible Notes include Dr. Hsiao and an affiliate of Dr. Frost.

On October 12, 2017, EirGen, our wholly-owned subsidiary, and Japan Tobacco Inc. ("JT") entered into a Development and License Agreement (the "JT Agreement") granting JT the exclusive rights for the development and commercialization of *Rayaldee* in Japan (the "JT Territory"). The license grant to JT covers the therapeutic and preventative use of *Rayaldee* for (i) SHPT in non-dialysis and dialysis patients with CKD, (ii) rickets, and (iii) osteomalacia, as well as such additional indications as may be added to the scope of the license subject to the terms of the JT Agreement. In connection with the

transaction, OPKO received an initial upfront payment of $6 million, and OPKO received another $6 million upon the initiation of OPKO's phase 2 study for *Rayaldee* in dialysis patients in the U.S. in September 2018. OPKO is also eligible to receive up to an additional aggregate amount of $31 million upon the achievement of certain regulatory and development milestones by JT for *Rayaldee* in the JT Territory, and $75 million upon the achievement of certain sales based milestones by JT in the JT Territory. OPKO will also receive tiered, double digit royalty payments at rates ranging from low double digits to mid-teens on sales of *Rayaldee* within the JT Territory. JT will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for *Rayaldee* in Japan and for all commercial activities pertaining to *Rayaldee* in Japan.

In May 2016, EirGen, our wholly-owned subsidiary, partnered with VFMCRP through a Development and License Agreement for the development and commercialization of *Rayaldee* in Europe, Canada, Mexico, Australia, South Korea and certain other international markets. 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"). We have received non-refundable and non-creditable payments of $52 million and are eligible to receive up to an additional $230 million upon the achievement of certain regulatory and sales-based milestones. 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 October 21, 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.

Top-line results from the study demonstrated that treatment with Somatrogon dosed once-weekly in pre-pubertal children with GHD was non-inferior to somatropin dosed once-daily with respect to height velocity at 12 months of treatment (the primary endpoint); the least square mean was higher in the Somatrogon group (10.12 cm/year) than in the somatropin group (9.78 cm/year); the treatment difference (Somatrogon – somatropin) in height velocity (cm/year) was 0.33 with a two-sided 95% confidence interval of the difference of (-0.39, 1.05). In addition, change in height standard deviation scores at six and twelve months, key secondary endpoints, were higher in the Somatrogon dosed once-weekly cohort in comparison to the somatropin dosed once-daily cohort. Moreover, at six months, change in height velocity, another key secondary endpoint, was higher in the Somatrogon dosed once-weekly cohort in comparison to the somatropin dosed once-daily cohort. These common measures of growth are employed in the clinical setting to measure the potential level of catch-up growth that subjects may experience relative to heights of age and gender matched peers.

Somatrogon was generally well tolerated in the study and comparable to that of somatropin dosed once-daily with respect to the types, numbers and severity of the adverse events observed between the treatment arms. Immunogenicity testing and analysis of additional data are ongoing, and full results of the study will be submitted for presentation at a future scientific meeting.

In 2014, Pfizer and OPKO entered into a worldwide agreement for the development and commercialization of our long-acting hGH-CTP 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 ("SGA"). 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 hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both hGH-CTP and Pfizer's Genotropin®.

Under the agreement, we agreed to lead the clinical activities and will be responsible for funding the development programs for the key indications, which includes Adult and Pediatric GHD and Pediatric SGA. Pfizer agreed to be responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer agreed to fund the commercialization activities for all indications and lead the manufacturing activities covered by the global development plan. The agreement obligated us to fund development up to an agreed cap

In December 2016, we announced preliminary topline data from our phase 3, double blind, placebo controlled study of hGH-CTP in adults with GHD. Although there was no statistically significant difference between hGH-CTP and placebo on the primary endpoint of change in trunk fat mass from baseline to 26 weeks, after unblinding the study, we identified an exceptional value of trunk fat mass reduction in the placebo group that may have affected the primary outcome. We have completed post-hoc sensitivity analyses to evaluate the influence of outliers on the primary endpoint results using multiple statistical approaches. Analyses that excluded outliers showed a statistically significant difference between hGH-CTP and placebo on the change in trunk fat mass. Additional analyses that did not exclude outliers showed mixed results. Following completion of the analyses, OPKO and Pfizer agreed that OPKO may proceed to discuss a possible BLA submission with the FDA. We believe there is a path for submission in which the FDA may assess the totality of the data, including all relevant efficacy and safety data in adult and pediatric patients. We will continue to assess the regulatory strategy for the adult indication going forward, including the timing of a possible submission.

The development project for hGH-CTP has exceeded our original estimates and will result in additional expenses beyond our estimates and the agreed development cap. If we are unable to reach an agreement with Pfizer regarding cost sharing for overruns, as well as other obligations, including development obligations, it could have a material adverse impact on the expected benefits of the Pfizer transaction and our overall financial condition. If we do not successfully develop hGH- CTP and/or Pfizer Inc. were to terminate the agreement or not successfully commercialize hGH-CTP for any reason, our business would be adversely affected.

We are constructing a research, development and manufacturing center in Waterford, Ireland, for which we will incur between $40 million and $50 million for the construction and validation of the facility. Construction of the facility began in the fourth quarter of 2016 with expected completion in 2019. Currently, we plan to fund the project from cash on hand or from third party funding sources that may be available to us. Through September 30, 2019, the cumulative expenditures we incurred to date on the construction of the facility was approximately $38.3 million.

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.

We expect to continue to incur substantial research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that selling, general and administrative expenses will also increase as we expand our sales, marketing and administrative staff and add infrastructure.

We believe that the cash and cash equivalents on hand atSeptember 30, 2019, the amounts available to be borrowed under our lines of credit and the proceeds from the issuance of 50 million shares of our common stock in October 2019 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 our relationship with Pfizer, the commercial success of *Rayaldee*, 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 not generated sustained positive cash flow and if we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions or reduce our marketing or sales efforts or cease operations.

The following table provides information as of September 30, 2019, 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, 2019	2020	2021	2022	2023	Thereafter	Total
Open purchase orders	$ 74,836	$ 2,589	$ 34	$ 9	$ —	$ —	$ 77,468
Operating leases	3,915	11,491	7,698	4,858	3,447	4,829	36,238
Finance leases	762	2,729	2,077	1,056	481	203	7,308
2033 Senior Notes, 2025 and 2023 Convertible Notes	—	—	—	—	3,050	201,260	204,310
Deferred payments	8,750	7,500	7,500	3,575	—	—	27,325
Mortgages and other debts payable	747	723	692	490	300	238	3,190
Lines of credit	5,484	50,644	—	—	—	—	56,128
Interest commitments	19	662	34	20	317	61,807	62,859
Total	$ 94,513	$ 76,338	$ 18,035	$ 10,008	$ 7,595	$ 268,337	$ 474,826

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 $149.1 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, 2018, that have a material impact to our Condensed Consolidated Financial Statements and related notes.

RECENT ACCOUNTING PRONOUNCEMENTS

Recently adopted accounting pronouncements.

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, “Leases (Topic 842),” which requires organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. ASU 2016-02, as amended and codified under Topic 842, requires new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. As required, we adopted Topic 842 on January 1, 2019 using the modified retrospective approach for all lease arrangements at the beginning or the period of adoption. Results for reporting periods beginning January 1, 2019 are presented under Topic 842, while prior period amounts were not adjusted and continue to be reported in accordance our historic accounting under ASC 840.

For leases that commenced before the effective date of Topic 842, we elected the permitted practical expedients to not reassess the following: (i) whether any expired or existing contracts contain leases (ii) the lease classification for any expired or existing leases and (iii) initial direct costs for any existing leases. We also elected the policy of not recording leases on our Condensed Consolidated Balance Sheet when the leases have a term 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 adoption of Topic 842 resulted in the recognition of operating lease liabilities of approximately$33.7 million and operating lease right-to-use assets of approximately $33.3 million as of March 31, 2019, primarily related to operating leases for our diagnostic facilities, based on the present value of lease payments over the lease term. There was no cumulative-effect adjustment to beginning Accumulated deficit on the Condensed Consolidated Balance Sheet. The accounting for our finance leases remains substantially unchanged, as finance lease liabilities and their corresponding right-to-use assets were already recorded on the Condensed Consolidated Balance Sheet under the previous guidance. The adoption of Topic 842 did not have a significant effect on our results of operations or cash flows. Refer to Note 15 for additional disclosures required by Topic 842.

In February 2018, the FASB issued ASU No. 2018-02, "Income Statement-Reporting Comprehensive Income (Topic 220)." This standard provides an option to reclassify stranded tax effects within accumulated other comprehensive loss to retained earnings due to the U.S. federal corporate income tax rate change in the Tax Cuts and Jobs Act of 2017. This standard is effective for interim and annual reporting periods beginning after December 15, 2018. We adopted this standard effective January 1, 2019 with the election not to reclassify immaterial amounts of stranded tax effects from accumulated other comprehensive loss to retained earnings.

In June 2018, the FASB issued ASU No. 2018-07, “Compensation - Stock Compensation (Topic 718),” which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The adoption of ASU 2018-07 on January 1, 2019, did not have a significant impact on our Condensed Consolidated Financial Statements.

Pending accounting pronouncements.

In June 2016, the FASB issued ASU No. 2016-13, “Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,” which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses rather than incurred losses to estimate credit losses on certain types of financial instruments, including trade receivables. This may result in the earlier recognition of allowances for losses. The ASU is effective for public entities for fiscal years beginning after December 15, 2019, 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, the Euro and the New Israeli Shekel.

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, 2019, we had cash and cash equivalents of$64.7 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2019 was less than 1%. As of September 30, 2019, the principal outstanding balance under BioReference's Credit Agreement with CB and our Chilean and Spanish lines of credit was $56.1 million in the aggregate at a weighted average interest rate of approximately4.4%.

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 Securities Exchange Act of 1934, as amended (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, 2019.

Changes to the Company's Internal Control Over Financial Reporting

We have implemented new controls as part of our effort to adopt Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)". The adoption of the ASU required the implementation of new accounting processes which necessitated changes to our internal controls over financial reporting.

There have been no changes to the Company's internal control over financial reporting that occurred during the quarter covered by this Quarterly Report on Form 10-Q 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, 2018 (the "Annual Report"), as updated by our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2019 and June 30, 2019. The following should be read in conjunction with the information provided in Part I, Item 3 of our Annual Report.

See Note 11 to the interim unaudited consolidated financial statements for information regarding the status of legal proceedings involving the Company.

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, 2018, and as described from time to time under "Risk Factors" in our subsequent filings with the Securities and Exchange Commission.

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*	Amendment No. 9 to Credit Agreement by and between BioReference Laboratories, Inc. and certain of its subsidiaries, and JPMorgan Chase, N.A. dated August 6, 2019.
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, 2019.
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, 2019.
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, 2019.
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, 2019.
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

* Filed herewith.

SIGNATURES

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

Date: November 5, 2019

OPKO Health, Inc.

/s/ Adam Logal

Adam Logal
Senior Vice President, Chief Financial Officer,
Chief Accounting Officer and Treasurer

AMENDMENT NO. 9 TO CREDIT AGREEMENT

AMENDMENT NO. 9 TO CREDIT AGREEMENT (this "Amendment"), dated as of August 6, 2019, is entered into among BIO-REFERENCE LABORATORIES, INC., a New Jersey corporation ("Company"), the Subsidiary Borrowers party hereto ("Subsidiary Borrowers," and together with Company, each a "Borrower" and, collectively, the "Borrowers"), the other Loan Parties party hereto, the Lenders party hereto, and JPMORGAN CHASE BANK, N.A., as the administrative agent for the Lenders (the "Administrative Agent").

W I T N E S S E T H :

WHEREAS, the Borrowers, the other Loan Parties party thereto, the Lenders party thereto, and the Administrative Agent have executed and delivered that certain Credit Agreement dated as of November 5, 2015, as amended by Amendment No. 1 to Credit Agreement dated as of February 29, 2016, as amended by Amendment No. 2 to Credit Agreement dated as of September 26, 2016, as amended by Amendment No. 3 to Credit Agreement dated as of March 17, 2017, as amended by Amendment No. 4 to Credit Agreement dated as of August 7, 2017, as amended by Amendment No. 5 to Credit Agreement dated as of November 8, 2017, as amended by Amendment No. 6 to Credit Agreement dated as of December 22, 2017, as amended by Waiver Under and Amendment No. 7 to Credit Agreement dated as of February 28, 2018, and as amended by Amendment No. 8 to Credit Agreement dated as of February 26, 2019 (as further amended, restated, supplemented, or otherwise modified from time to time prior to the date hereof, the "Credit Agreement"); and

WHEREAS, the Borrowers have requested that the Lenders and the Administrative Agent make certain amendments to the Credit Agreement, and the Lenders party hereto, constituting all Lenders under the Credit Agreement, have agreed to such amendments, subject to the terms and conditions hereof.

NOW, THEREFORE, for and in consideration of the above premises and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged by the parties hereto, each of the Borrowers, the other Loan Parties, the Lenders and the Administrative Agent hereby covenant and agree as follows:

SECTION 1. Definitions. Unless otherwise specifically defined herein, each term used herein (and in the recitals above) which is defined in the Credit Agreement shall have the meaning assigned to such term in the Credit Agreement. As of the date hereof, each reference in the Credit Agreement to "this Agreement," "hereunder," "hereof," "herein," or words of like import, and each reference in the other Loan Documents to the Credit Agreement (including, without limitation, by means of words like "thereunder," "thereof" and words of like import), shall mean and be a reference to the Credit Agreement, as amended hereby.

SECTION 2. Amendment to Credit Agreement. Effective upon the satisfaction of the conditions precedent set forth in Section 3, the Credit Agreement is hereby amended as follows:

(a) Section 1.01 of the Credit Agreement is hereby amended by adding the following definition of "Amendment No. 9 Effective Date" in appropriate alphabetical order:

"Amendment No. 9 Effective Date" means August 6, 2019.

(b) Each of the following definitions in Section 1.01 of the Credit Agreement is hereby amended so that it reads, in its entirety, as follows:

"Dominion Period" means, on and after the Amendment No. 9 Effective Date, (a) any period during which any Event of Default has occurred and is continuing or (b) any period (i) commencing at any time when FCCR Availability shall be less than 10.0% of the Aggregate Revolving Commitment under this clause (b), for a period of at least five (5) consecutive Business Days, and (ii) ending when (y) FCCR Availability shall have been greater than 10.0% of the Aggregate Revolving Commitment for a period of sixty (60) consecutive days and (z) the Fixed Charge Coverage Ratio as of the last day of the most recently ended fiscal quarter is not less than 1.0 to 1.0.

"FCCR Availability" means, at any time on and after the Amendment No. 9 Effective Date, an amount equal to the sum of (a) the lesser of (i) the Aggregate Revolving Commitment and (ii) the Borrowing Base (provided, however, for the purposes of calculating FCCR Availability for Section 6.12 only, the $5,000,000 Reserve imposed by the Administrative Agent prior to the Amendment No. 9 Effective Date which is applicable to all Borrowing Base Certificates delivered on and after January 2019 shall be disregarded) plus (b) Qualified Cash in an amount approved by the Administrative Agent in its sole discretion not to exceed $5,000,000minus (c) the Aggregate Revolving Exposure (calculated, with respect to any Defaulting Lender, as if such Defaulting Lender had funded its Applicable Percentage of all outstanding Borrowings), all as determined by the Administrative Agent in its Permitted Discretion in accordance with this Agreement.

"Increased Reporting Period" means, on and after the Amendment No. 9 Effective Date, any period (a) commencing either (i) on the date on which the Administrative Agent sends notice to the Borrower (which notice may be provided via e-mail in accordance with Section 9.01) that Modified Availability has been less than 15% of the Aggregate Revolving Commitment for a period of five (5) consecutive Business Days, or (ii) upon the occurrence and continuance of an Event of Default, and (b) ending on the date on which Modified Availability has been equal to or greater than 15% of the Aggregate Revolving Commitment for a period of ten (10) consecutive days, so long as no Event of Default is in existence.

"Modified Availability" means, at any time on and after the Amendment No. 9 Effective Date, an amount equal to the sum of (a) the lesser of (i) the Aggregate Revolving Commitment and (ii) the Borrowing Base plus (b) Qualified Cash in an amount not to exceed $7,500,000minus (c) the Aggregate Revolving Exposure (calculated, with respect to any Defaulting Lender, as if such Defaulting Lender had funded its Applicable Percentage of all outstanding Borrowings), all as determined by the Administrative Agent in its Permitted Discretion in accordance with this Agreement.

(c) Section 6.12 of the Credit Agreement is hereby amended so it reads, in its entirety, as follows:

Section 6.12 Fixed Charge Coverage Ratio. The Borrowers will not permit the Fixed Charge Coverage Ratio as of the last day of any fiscal quarter, commencing with the fiscal quarter ending immediately preceding the date on which the Borrowers' FCCR Availability is less than 10.0% of the Aggregate Revolving Commitment, to be less than 1.0 to 1.0. Once such covenant is in effect, compliance with the covenant will be discontinued, so long as no Event of Default shall have occurred and be continuing: (i) on the day immediately succeeding the last day of the fiscal quarter which includes the 30th consecutive day on which the Borrowers' FCCR Availability remains in excess of 10.0% of the Aggregate Revolving Commitment, and (ii) no more than three (3) times in any period of twelve (12) consecutive months. Notwithstanding anything in this Section 6.12 to the contrary,

compliance with the foregoing covenant will not be tested for the fiscal quarter ending (i) June 30, 2019 and (ii) September 30, 2019, so long as, in the case of clause (ii), (A) no Event of Default shall have occurred and be continuing and (B) the Borrowers' FCCR Availability shall have been in excess of 10.0% of the Aggregate Revolving Commitment for the 30 consecutive day period ending on September 30, 2019.

SECTION 3. Conditions Precedent. This Amendment shall become effective on the date the following conditions precedent shall have been satisfied:

(a) receipt by the Administrative Agent of signatures to this Amendment from the parties listed on the signature pages hereto; and

(b) the Administrative Agent shall have received from the Borrowers (or the Administrative Agent shall be satisfied with arrangements made for the payment thereof) all other costs, fees, and expenses owed by the Borrowers to the Administrative Agent in connection with this Amendment, including, without limitation, reasonable attorneys' fees and expenses, in accordance with Section 9.03 of the Credit Agreement.

SECTION 4. Miscellaneous.

(a) Representations and Warranties. To induce the Administrative Agent and Lenders to enter into this Amendment, the Borrowers hereby represent and warrant to the Administrative Agent and the Lenders that all representations and warranties of the Borrowers contained in Article III of the Credit Agreement or any other Loan Document are true and correct in all material respects with the same effect as though made on and as of the date hereof (except with respect to representations and warranties made as of an expressed date, which representations and warranties are true and correct in all material respects as of such date).

(b) No Offset. To induce the Administrative Agent and Lenders to enter into this Amendment, the Borrowers hereby acknowledge and agree that, as of the date hereof, and after giving effect to the terms hereof, there exists no right of offset, defense, counterclaim, claim, or objection in favor of the Borrowers or arising out of or with respect to any of the loans or other obligations of the Borrowers owed by the Borrowers under the Credit Agreement or any other Loan Document.

(c) Loan Document. The parties hereto hereby acknowledge and agree that this Amendment is a Loan Document.

(d) Effect of Amendment. Except as set forth expressly herein, all terms of the Credit Agreement and the other Loan Documents shall be and remain in full force and effect, and shall constitute the legal, valid, binding, and enforceable obligations of the Borrowers, enforceable in accordance with their terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other laws affecting creditors' rights generally and subject to general principles of equity, regardless of whether considered in a proceeding in equity or at law.

(e) No Novation or Mutual Departure. The Borrowers expressly acknowledge and agree that (i) this Amendment does not constitute or establish, a novation with respect to the Credit

Agreement or any of the other Loan Documents, or a mutual departure from the strict terms, provisions, and conditions thereof, other than with respect to the amendments set forth in Section 2 above, and (ii) nothing in this Amendment shall affect or limit the Administrative Agent's or any Lender's right to (x) demand payment of the Obligations under, or demand strict performance of the terms, provisions and conditions of, the Credit Agreement and the other Loan Documents (in each case, as amended), as applicable, (y) exercise any and all rights, powers, and remedies under the Credit Agreement or the other Loan Documents (in each case, as amended hereby) or at law or in equity, or (z) do any and all of the foregoing, immediately at any time during the occurrence of an Event of Default and in each case, in accordance with the terms and provisions of the Credit Agreement and the other Loan Documents (in each case, as amended hereby).

(f) Counterparts. This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed and delivered shall be deemed to be an original and all of which counterparts, taken together, shall constitute but one and the same instrument. This Amendment may be executed by each party on separate copies, which copies, when combined so as to include the signatures of all parties, shall constitute a single counterpart of this Amendment.

(g) Fax or Other Transmission. Delivery by one or more parties hereto of an executed counterpart of this Amendment via facsimile, telecopy, or other electronic method of transmission pursuant to which the signature of such party can be seen (including, without limitation, Adobe Corporation's Portable Document Format) shall have the same force and effect as the delivery of an original executed counterpart of this Amendment. Any party delivering an executed counterpart of this Amendment by facsimile or other electronic method of transmission shall also deliver an original executed counterpart, but the failure to do so shall not affect the validity, enforceability, or binding effect of this Amendment.

(h) Recitals Incorporated Herein. The preamble and the recitals to this Amendment are hereby incorporated herein by this reference.

(i) Section References. Section titles and references used in this Amendment shall be without substantive meaning or content of any kind whatsoever and are not a part of the agreements among the parties hereto evidenced hereby.

(j) Governing Law. This Amendment shall be governed by and construed in accordance with the internal laws (and not the law of conflicts) of the State of New York, but giving effect to federal laws applicable to national banks.

(k) Severability. Any provision of this Amendment which is prohibited or unenforceable shall be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof in that jurisdiction or affecting the validity or enforceability of such provision in any other jurisdiction.

(l) Reaffirmation of Loan Parties. Each Loan Party (i) consents to the execution and delivery of this Amendment, (ii) reaffirms all of its obligations and covenants under the Loan Documents (including, without limitation, the Collateral Documents and the Loan Guaranty) to

which it is a party, and (iii) agrees that, except to the extent amended hereby, none of its respective obligations and covenants under the Loan Documents shall be reduced or limited by the execution and delivery of this Amendment.

[SIGNATURES ON FOLLOWING PAGES.]

IN WITNESS WHEREOF, the Borrowers, the other Loan Parties, the Administrative Agent and the Lenders have caused this Amendment to be duly executed by their respective duly authorized officers as of the day and year first above written.

BORROWERS:

BIO-REFERENCE LABORATORIES, INC.

GENEDX, INC.

FLORIDA CLINICAL LABORATORY, INC.

MERIDIAN CLINICAL LABORATORY CORP.

By: /s/Adam Logal

Name: Adam Logal

Title: Vice President

OTHER LOAN PARTIES:

CAREEVOLVE.COM, INC.

BRLI-GENPATH DIAGNOSTICS, INC.

GENEDX MENA LLC

By: /s/Adam Logal

Name: Adam Logal

Title: Vice President

JPMORGAN CHASE BANK, N.A.,

Individually as a Lender and as Administrative Agent, Issuing Bank and Swingline Lender

By: /s/Antje Focke

Name: Antje Focke

Title: Executive Director

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: November 5, 2019

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.

Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Adam Logal, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2019

/s/ Adam Logal

Adam Logal

Senior Vice President, Chief Financial Officer,
Chief Accounting Officer and Treasurer

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, 2019 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2019

/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, 2019 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2019

/s/ Adam Logal

Adam Logal

Senior Vice President, Chief Financial Officer
Chief Accounting Officer and Treasurer