
**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 June 30, 2021.

OR

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

For the transition period from _____ to _____.

Commission file number 001-33528

OPKO Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

75-2402409
(I.R.S. Employer
Identification No.)

4400 Biscayne Blvd.
Miami FL 33137

(Address of Principal Executive Offices) (Zip Code)

(305) 575-4100

(Registrant's Telephone Number, Including Area Code)

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

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

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

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

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

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

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

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

As of July 20, 2021, the registrant had 681,162,619 shares of Common Stock outstanding.

TABLE OF CONTENTS

	<u>Page</u>
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1.</u> <u>Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets as of June 30, 2021 and December 31, 2020 (unaudited)</u>	<u>7</u>
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2021 and 2020 (unaudited)</u>	<u>8</u>
<u>Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended June 30, 2021 and 2020 (unaudited)</u>	<u>9</u>
<u>Condensed Consolidated Statements of Equity for the three and six months ended June 30, 2021 and 2020 (unaudited)</u>	<u>10</u>
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2021 and 2020 (unaudited)</u>	<u>12</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>13</u>
<u>Item 2.</u> <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>44</u>
<u>Item 3.</u> <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>62</u>
<u>Item 4.</u> <u>Controls and Procedures</u>	<u>63</u>
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1.</u> <u>Legal Proceedings</u>	<u>64</u>
<u>Item 1A.</u> <u>Risk Factors</u>	<u>66</u>
<u>Item 2.</u> <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>66</u>
<u>Item 3.</u> <u>Defaults Upon Senior Securities</u>	<u>66</u>
<u>Item 4.</u> <u>Mine Safety Disclosures</u>	<u>66</u>
<u>Item 5.</u> <u>Other Information</u>	<u>66</u>
<u>Item 6.</u> <u>Exhibits</u>	<u>67</u>
<u>Signatures</u>	<u>68</u>

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains “forward-looking statements,” as that term is defined under the Private Securities Litigation Reform Act of 1995 (“PSLRA”), Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects, including the potential impact of the COVID-19 pandemic on our businesses, operating results, cash flows and/or financial condition. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in “Item 1A-Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2020, and described from time to time in our other filings with the Securities and Exchange Commission (the “SEC”). We do not undertake any obligation to update forward-looking statements, except to the extent required by applicable law. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

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

- our business may be materially adversely affected by the coronavirus (COVID-19) pandemic, including the impact on our sales and operations from continued or increasing infection rates and potential declines in testing needs should infection rates decline;
- we have had a history of losses and may not generate sustained positive cash flow sufficient to fund our operations and research and development programs;
- our need for, and ability to obtain, additional financing when needed on favorable terms, or at all;
- adverse results in material litigation matters or governmental inquiries;
- the risks inherent in developing, obtaining regulatory approvals for and commercializing new, commercially viable and competitive products and treatments;
- our research and development activities may not result in commercially viable products;
- that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results;
- that we may fail to obtain regulatory approval for hGH-CTP (Somatrogen) or successfully commercialize hGH-CTP (Somatrogen);
- that we may not generate or sustain profits or cash flow from our laboratory operations or substantial revenue from *Royaldee* and our other pharmaceutical and diagnostic products;
- that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied;
- our ability and our distribution and marketing partners’ ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates and the operation of our laboratories;
- the performance of our third-party distribution partners, licensees and manufacturers over which we have limited control;
- changes in regulation and policies in the United States (“U.S.”) and other countries, including increasing downward pressure on healthcare reimbursement;
- our ability to manage our growth and our expanded operations;
- increased competition, including price competition;
- changing relationships with payors, including the various state and multi-state programs, suppliers and strategic partners;
- efforts by third-party payors to reduce utilization and reimbursement for clinical testing services;

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

PART I. FINANCIAL INFORMATION

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

Item 1. Financial Statements

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

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 65,757	\$ 72,211
Accounts receivable, net	265,856	286,314
Inventory, net	134,722	132,341
Other current assets and prepaid expenses	47,627	32,313
Assets held for sale	33,067	—
Total current assets	547,029	523,179
Property, plant and equipment, net	106,652	140,554
Intangible assets, net	445,515	475,002
In-process research and development	590,200	590,200
Goodwill	677,360	680,602
Investments	8,945	15,731
Operating lease right-of-use assets	36,349	37,735
Other assets	9,600	10,060
Total assets	\$ 2,421,650	\$ 2,473,063
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 88,512	\$ 100,883
Accrued expenses	187,172	240,869
Current maturities of operating leases	10,102	9,028
Liabilities associated with assets held-for-sale	233	—
Current portion of lines of credit and notes payable	17,961	24,703
Total current liabilities	303,980	375,483
Operating lease liabilities	30,605	29,760
Convertible notes	183,198	221,989
Deferred tax liabilities	136,416	137,208
Other long-term liabilities, principally contract liabilities, contingent consideration and lines of credit	24,866	37,072
Total long-term liabilities	375,085	426,029
Total liabilities	679,065	801,512
Equity:		
Common Stock - \$0.01 par value, 1,000,000,000 shares authorized; 689,817,971 and 670,585,576 shares issued at June 30, 2021 and December 31, 2020, respectively	6,898	6,706
Treasury Stock - 8,655,082 and 549,907 shares at June 30, 2021 and December 31, 2020, respectively	(1,791)	(1,791)
Additional paid-in capital	3,214,351	3,152,694
Accumulated other comprehensive loss	(9,932)	(4,225)
Accumulated deficit	(1,466,941)	(1,481,833)
Total shareholders' equity	1,742,585	1,671,551
Total liabilities and equity	\$ 2,421,650	\$ 2,473,063

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

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

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Revenues:				
Revenue from services	\$ 397,197	\$ 250,971	\$ 904,149	\$ 421,811
Revenue from products	35,663	29,356	69,608	60,430
Revenue from transfer of intellectual property and other	9,548	20,880	13,816	30,433
Total revenues	<u>442,408</u>	<u>301,207</u>	<u>987,573</u>	<u>512,674</u>
Costs and expenses:				
Cost of service revenue	267,807	144,794	607,235	267,680
Cost of product revenue	25,101	17,857	49,179	35,229
Selling, general and administrative	113,236	77,721	225,522	153,852
Research and development	18,222	17,608	37,537	39,369
Contingent consideration	(103)	1,111	(1,059)	251
Amortization of intangible assets	12,574	14,937	25,151	29,874
Total costs and expenses	<u>436,837</u>	<u>274,028</u>	<u>943,565</u>	<u>526,255</u>
Operating income (loss)	5,571	27,179	44,008	(13,581)
Other income and (expense), net:				
Interest income	6	5	12	147
Interest expense	(4,887)	(5,474)	(10,282)	(10,970)
Fair value changes of derivative instruments, net	(272)	(13)	(711)	608
Other income (expense), net	(11,783)	18,223	(12,711)	5,890
Other income and (expense), net	<u>(16,936)</u>	<u>12,741</u>	<u>(23,692)</u>	<u>(4,325)</u>
Income (loss) before income taxes and investment losses	(11,365)	39,920	20,316	(17,906)
Income tax provision	(4,754)	(6,028)	(5,314)	(7,200)
Net income (loss) before investment losses	(16,119)	33,892	15,002	(25,106)
Loss from investments in investees	(67)	(189)	(110)	(323)
Net income (loss)	<u>\$ (16,186)</u>	<u>\$ 33,703</u>	<u>\$ 14,892</u>	<u>\$ (25,429)</u>
Income (loss) per share, basic and diluted:				
Income (loss) per share	\$ (0.03)	\$ 0.05	\$ 0.02	\$ (0.04)
Weighted average common shares outstanding, basic and diluted	646,996,891	640,578,794	644,001,280	640,578,794

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

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

	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Net income (loss)	\$ (16,186)	\$ 33,703	\$ 14,892	\$ (25,429)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss)	3,363	4,435	(5,707)	(3,682)
Comprehensive income (loss)	\$ (12,823)	\$ 38,138	\$ 9,185	\$ (29,111)

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

CONSOLIDATED STATEMENTS OF EQUITY
(Unaudited)
(In thousands, except share data)
For the three and six months ended June 30, 2021

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Income (loss)	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at March 31, 2021	670,703,076	\$ 6,707	(549,907)	\$ (1,791)	\$ 3,155,648	\$ (13,295)	\$ (1,450,755)	\$ 1,696,514
Equity-based compensation expense	—	—	—	—	3,460	—	—	3,460
Exercise of Common Stock options and warrants	63,625	1	—	—	158	—	—	159
Conversion of 2025 convertible notes	19,051,270	190	(8,105,175)	—	55,085	—	—	55,275
Net loss	—	—	—	—	—	—	(16,186)	(16,186)
Other comprehensive income	—	—	—	—	—	3,363	—	3,363
Balance at June 30, 2021	689,817,971	\$ 6,898	(8,655,082)	\$ (1,791)	\$ 3,214,351	\$ (9,932)	\$ (1,466,941)	\$ 1,742,585

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2020	670,585,576	\$ 6,706	(549,907)	\$ (1,791)	\$ 3,152,694	\$ (4,225)	\$ (1,481,833)	\$ 1,671,551
Equity-based compensation expense	—	—	—	—	6,107	—	—	6,107
Exercise of Common Stock options and warrants	181,125	2	—	—	465	—	—	467
Conversion of 2025 convertible notes	19,051,270	190	(8,105,175)	—	55,085	—	—	55,275
Net income	—	—	—	—	—	—	14,892	14,892
Other comprehensive loss	—	—	—	—	—	(5,707)	—	(5,707)
Balance at June 30, 2021	689,817,971	\$ 6,898	(8,655,082)	\$ (1,791)	\$ 3,214,351	\$ (9,932)	\$ (1,466,941)	\$ 1,742,585

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

CONSOLIDATED STATEMENTS OF EQUITY
(Unaudited)
(In thousands, except share data)
For the three and six months ended June 30, 2020

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at March 31, 2020	670,378,701	\$ 6,704	(549,907)	\$ (1,791)	\$ 3,145,444	\$ (30,187)	\$ (1,571,551)	\$ 1,548,619
Equity-based compensation expense	—	—	—	—	1,586	—	—	1,586
Net income	—	—	—	—	—	—	33,703	33,703
Other comprehensive income	—	—	—	—	—	4,435	—	4,435
Balance at June 30, 2020	670,378,701	\$ 6,704	(549,907)	\$ (1,791)	\$ 3,147,030	\$ (25,752)	\$ (1,537,848)	\$ 1,588,343

	Common Stock		Treasury		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Dollars	Shares	Dollars				
Balance at December 31, 2019	670,378,701	\$ 6,704	(549,907)	\$ (1,791)	\$ 3,142,993	\$ (22,070)	\$ (1,511,077)	\$ 1,614,759
Equity-based compensation expense	—	—	—	—	4,037	—	—	4,037
Adoption of ASC 326	—	—	—	—	—	—	(1,342)	(1,342)
Net loss	—	—	—	—	—	—	(25,429)	(25,429)
Other comprehensive loss	—	—	—	—	—	(3,682)	—	(3,682)
Balance at June 30, 2020	670,378,701	\$ 6,704	(549,907)	\$ (1,791)	\$ 3,147,030	\$ (25,752)	\$ (1,537,848)	\$ 1,588,343

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 six months ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net income (loss)	\$ 14,892	\$ (25,429)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	40,561	44,318
Non-cash interest	4,981	5,022
Amortization of deferred financing costs	424	411
Losses from investments in investees	110	323
Equity-based compensation – employees and non-employees	6,107	4,037
Realized loss (gain) on disposal of fixed assets and sales of equity securities	(3,146)	156
Loss on conversion of the 2025 Notes	11,111	—
Change in fair value of equity securities and derivative instruments	873	(6,515)
Change in fair value of contingent consideration	(1,059)	251
Deferred income tax provision	2,479	1,028
Changes in assets and liabilities:		
Accounts receivable, net	20,352	(81,539)
Inventory, net	(3,817)	(21,905)
Other current assets and prepaid expenses	(13,904)	(2,619)
Other assets	1,388	(61)
Accounts payable	(11,651)	(16,753)
Foreign currency measurement	(2,532)	(2,077)
Contract liabilities	(7,425)	(4,026)
Accrued expenses and other liabilities	(49,160)	47,585
Net cash provided by (used in) operating activities	10,584	(57,793)
Cash flows from investing activities:		
Proceeds from sale of investments	8,079	—
Proceeds from the sale of property, plant and equipment	165	65
Capital expenditures	(18,192)	(17,149)
Net cash used in investing activities	(9,948)	(17,084)
Cash flows from financing activities:		
Proceeds from the exercise of common stock options and warrants	466	—
Borrowings on lines of credit	982,797	393,651
Repayments of lines of credit	(990,190)	(382,374)
Net cash provided by (used in) financing activities	(6,927)	11,277
Effect of exchange rate changes on cash and cash equivalents	(163)	(240)
Net decrease in cash and cash equivalents	(6,454)	(63,840)
Cash and cash equivalents at beginning of period	72,211	85,452
Cash and cash equivalents at end of period	\$ 65,757	\$ 21,612
SUPPLEMENTAL INFORMATION:		
Interest paid	\$ 4,883	\$ 5,578
Income taxes paid, net of refunds	\$ 3,690	\$ (208)
Non-cash financing:		
Shares issued upon the conversion of:		
2025 Convertible Notes	\$ 68,775	\$ —

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

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

NOTE 1 BUSINESS AND ORGANIZATION

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories, Inc. (“BioReference”), one of the nation’s largest full service laboratories with a core genetic testing business and an almost 300-person sales and marketing team to drive growth and leverage new products, including the *4Kscore* test. Our pharmaceutical business features *Rayaldee*, a U.S. Food and Drug Administration (“FDA”) approved treatment for secondary hyperparathyroidism (“SHPT”) in adults with stage 3 or 4 chronic kidney disease (“CKD”) and vitamin D insufficiency (launched in November 2016) and a pipeline of products in various stages of development. Our leading product in development is Somatrogen (hGH-CTP), a once-weekly human growth hormone for which we have partnered with Pfizer, Inc. (“Pfizer”) and successfully completed a phase 3 study in August 2019, and for which the FDA has accepted the initial Biologics License Application (“BLA”) for filing. We have also submitted a New Drug Application (an “NDA”) with the Ministry of Health, Labour and Welfare in Japan and a Marketing Authorization Application with the European Medicines Agency. We are incorporated in Delaware, and our principal executive offices are located in leased offices in Miami, Florida.

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

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

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

In June 2021, we announced that EirGen Pharma Limited (“EirGen”), our wholly owned subsidiary, entered into a definitive agreement to sell one of its facilities in Waterford, Ireland to Horizon Therapeutics plc for \$65 million in cash less certain assumed and accrued liabilities relating to transferred employees. The facility houses EirGen’s sterile-fill-finish business and is no longer a core component of our ongoing operations and business strategy. The transaction closed in the third quarter of 2021. As of June 30, 2021, the facility met the held-for-sale accounting criteria and the related assets and liabilities are classified as held for sale in the condensed consolidated balance sheet. We recognized a gain on the sale of the facility in the third quarter 2021 of \$32.4 million. The facility was included in our pharmaceutical segment as of June 30, 2021.

NOTE 2 IMPACT OF COVID-19

As the disease caused by SARS-CoV-2, a novel strain of coronavirus, COVID-19 continues to spread and severely impact the U.S. economy and economies of other countries around the world, we are committed to being a part of the coordinated public and private sector response to this unprecedented challenge. In response to the COVID-19 pandemic, BioReference is providing COVID-19 solutions, including diagnostic molecular testing and serology antibody testing, to meet the testing needs of its numerous customer verticals, including physicians, health systems, long-term care facilities, governments, schools, employers, professional sports teams and entertainment venues, as well as the general public through relationships with retail pharmacy chains.

Revenue from services for the six months ended June 30, 2021 increased by \$82.3 million as compared to 2020 due to COVID-19 testing volumes; however we are unable to predict how long the demand will continue for our COVID-19 related testing, or whether pricing and reimbursement policies for testing will sustain, and accordingly, the sustainability of our COVID-19 testing volumes is uncertain. Additionally, beginning in March 2020, BioReference experienced a decline in routine testing volumes due to the COVID-19 pandemic; however as stay at home orders and other restrictions have been lifted, we have seen our routine clinical and genomic testing volumes trending towards normalization with prior periods. Should stay

at home orders or other restrictions be reenacted, we could see our routine testing levels decline. Excluding COVID-19 test volumes, for the six months ended June 30, 2021, genomic and routine clinical test volume increased 39% and 13.4% as compared to volumes for the six months ended June 30, 2020. Additionally, sales of *Rayaldee* have not increased in accordance with its expected growth trajectory as a result of challenges in onboarding new patients due to the COVID-19 pandemic. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, customers closing or severely curtailing their operations (voluntarily or in response to government orders), and the adoption of work-from-home or shelter-in-place policies. We also continue to see a substantial need for COVID-19 testing by our existing clients and expect new clients as infections for the virus continue.

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

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

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

Since the pandemic began in the U.S., we have invested in testing capabilities and infrastructure to meet demand for our molecular and antibody testing for COVID-19.

NOTE 3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation. The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and notes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments or adjustments otherwise disclosed herein) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three and six months ended June 30, 2021 are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2021 or any other future periods. The unaudited Condensed Consolidated Financial Statements should be read in conjunction with the audited Consolidated Financial Statements and the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2020.

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

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

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

Inventories. Inventories are valued at the lower of cost and net realizable value. Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost and net realizable value. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories. Inventory obsolescence expense for the three and six months ended June 30, 2021 was \$0.9 million and \$3.9 million, respectively. Inventory obsolescence expense for the three and six months ended June 30, 2020 was \$1.1 million and \$1.7 million, respectively.

Pre-launch inventories. We may accumulate commercial quantities of certain product candidates prior to the date we anticipate that such products will receive final FDA approval. The accumulation of such pre-launch inventories 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 5. Goodwill, in-process research and development (“IPR&D”) and other intangible assets acquired in business combinations, licensing and other transactions was \$1.7 billion at both June 30, 2021 and December 31, 2020.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. At acquisition, we generally determine the fair value of intangible assets, including IPR&D, using the “income method.”

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

Goodwill was \$677.4 million and \$680.6 million, respectively, at June 30, 2021 and December 31, 2020. Estimating the fair value of a reporting unit for goodwill impairment is highly sensitive to changes in projections and assumptions and changes in assumptions could potentially lead to impairment. We perform sensitivity analyses around our assumptions in order to assess the reasonableness of the assumptions and the results of our testing. Ultimately, potential changes in these assumptions may impact the estimated fair value of a reporting unit and result in an impairment if the fair value of such reporting unit is less than its carrying value.

Net intangible assets other than goodwill was \$1.0 billion and \$1.1 billion, including IPR&D of \$590.2 million, at June 30, 2021 and December 31, 2020, respectively. Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products and IPR&D. Considering the high risk nature of research and development and the industry’s success rate of bringing developmental compounds to market, IPR&D impairment charges may occur in future periods. Estimating the fair value of IPR&D for potential impairment is highly sensitive to changes in projections and assumptions and changes in assumptions could potentially lead to impairment.

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

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

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging 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 \$25.2 million and \$29.9 million for the six months ended June 30, 2021 and 2020, respectively.

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

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

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

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

Property, plant and equipment. Property, plant and equipment are recorded at cost or fair value if acquired in a business combination. Depreciation is provided using the straight-line method over the estimated useful lives of the assets and includes amortization expense for assets capitalized under finance leases. The estimated useful lives by asset class are as follows: software - 3 years, machinery, medical and other equipment - 5-8 years, furniture and fixtures - 5-12 years, leasehold improvements - the lesser of their useful life or the lease term, buildings and improvements - 10-40 years, and automobiles - 3-5 years. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation expense was \$8.0 million and \$15.4 million for the three and six months ended June 30, 2021, respectively. Depreciation expense was \$7.3 million and \$14.4 million for the three and six months ended June 30, 2020, respectively. Assets held under finance leases are included within Property, plant and equipment, net in our Condensed Consolidated Balance Sheet and are amortized over the shorter of their useful lives or the expected term of their related leases. Assets to be disposed of by sale are recognized as held for sale at the lower of carrying value or fair value less costs to sell.

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

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

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

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

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

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

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

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk because the related healthcare programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. At June 30, 2021 and December 31, 2020, receivable balances (net of explicit and implicit price concessions) from Medicare and Medicaid were 5% and 6%, respectively, of our consolidated Accounts receivable, net. At June 30, 2021 and December 31, 2020, receivable balances (net of explicit and implicit price concessions) due directly from states, cities and other municipalities, specifically related to our real-time reverse-transcription polymerase chain reaction (real-time RT-PCR) assay to detect COVID-19, were 7.1% and 6.3% of our consolidated accounts receivable, net, respectively.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At June 30, 2021 and December 31, 2020, receivables due from patients represented approximately 1.0% and 0.7%, respectively, of our consolidated Accounts receivable, net.

We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer’s ability to pay. Actual results could differ from those estimates. The allowance for credit losses was \$2.5 million and \$2.1 million at June 30, 2021 and December 31, 2020, respectively. The credit loss expense for the three and six months ended June 30, 2021 was \$0.3 million and \$0.6 million, respectively. The credit loss expense for the three and six months ended June 30, 2020 was \$0.1 million and \$0.2 million, respectively.

Equity-based compensation. We measure the cost of services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits realized from the exercise of stock options as cash flows from operations. For the three and six months ended June 30, 2021 we recorded \$3.5 million and \$6.1 million, respectively, of equity-based compensation expense. For the three and six months ended June 30, 2020, we recorded \$1.6 million and \$4.0 million, respectively, of equity-based compensation expense.

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

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

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

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

Foreign currency translation. The financial statements of certain of our foreign operations are measured using the local currency as the functional currency. The local currency assets and liabilities are generally translated at the rate of exchange to the U.S. dollar on the balance sheet date and the local currency revenues and expenses are translated at average rates of exchange to the U.S. dollar during the reporting periods. Foreign currency transaction gains (losses) have been reflected as a component of Other income (expense), net within the Condensed Consolidated Statement of Operations and foreign currency translation gains (losses) have been included as a component of the Condensed Consolidated Statement of Comprehensive Income (Loss).

Variable interest entities. The consolidation of a variable interest entity (“VIE”) is required when an enterprise has a controlling financial interest. A controlling financial interest in a VIE will have both of the following characteristics: (a) the power to direct the activities of a VIE that most significantly impact the VIE’s economic performance and (b) the obligation to absorb losses of the VIE that could potentially be significant to the VIE. Refer to Note 6.

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

Pending accounting pronouncements.

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

NOTE 4 EARNINGS (LOSS) PER SHARE

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

A total of 64,292,882 and 69,505,513 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the three months ended June 30, 2021, and 2020, respectively, because their inclusion would be antidilutive. A total of 69,861,689 and 69,347,867 potential shares of Common Stock were excluded from the calculation of diluted net loss per share for the six months ended June 30, 2021, and 2020, respectively, because their inclusion would be antidilutive. A full presentation of diluted earnings per share has not been provided because the required adjustments to the numerator and denominator resulted in diluted earnings per share equivalent to basic earnings per share.

During the three months ended June 30, 2021, 63,625 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 63,625 shares of Common Stock. Of the 63,625 Common Stock options and Common Stock warrants exercised, no shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the six months ended June 30, 2021, 181,125 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 181,125 shares of Common Stock. Of the 181,125 Common Stock options and Common Stock warrants exercised, no shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the three and six months ended June 30, 2020, 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.

NOTE 5 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

<u>(In thousands)</u>	June 30, 2021	December 31, 2020
Accounts receivable, net:		
Accounts receivable	\$ 268,327	\$ 288,369
Less: allowance for credit losses	(2,471)	(2,055)
	<u>\$ 265,856</u>	<u>\$ 286,314</u>
Inventories, net:		
Consumable supplies	\$ 90,838	\$ 86,779
Finished products	38,870	36,831
Work in-process	3,449	5,268
Raw materials	6,409	5,784
Less: inventory reserve	(4,844)	(2,321)
	<u>\$ 134,722</u>	<u>\$ 132,341</u>
Other current assets and prepaid expenses:		
Taxes recoverable	\$ 9,291	\$ 13,440
Prepaid expenses	14,593	7,259
Prepaid insurance	7,374	3,803
Other receivables	492	2,502
Other	15,877	5,309
	<u>\$ 47,627</u>	<u>\$ 32,313</u>
Intangible assets, net:		
Customer relationships	\$ 447,484	\$ 448,751
Technologies	290,582	296,623
Trade names	49,806	49,820
Covenants not to compete	16,328	16,334
Licenses	5,766	5,766
Product registrations	7,803	8,025
Other	6,351	6,513
Less: accumulated amortization	(378,605)	(356,830)
	<u>\$ 445,515</u>	<u>\$ 475,002</u>
Accrued expenses:		
Inventory received but not invoiced	\$ 33,478	\$ 72,160
Commitments and contingencies	23,161	15,454
Employee benefits	40,899	43,300
Contract liabilities	8,400	15,783
Clinical trials	6,116	7,112
Contingent consideration	487	1,188
Finance leases short-term	2,084	2,453
Professional fees	3,347	4,985
Other	69,200	78,434
	<u>\$ 187,172</u>	<u>\$ 240,869</u>

(In thousands)	June 30, 2021	December 31, 2020
Other long-term liabilities:		
Contingent consideration	\$ 2,987	\$ 4,507
Mortgages and other debts payable	3,970	3,837
Finance leases long-term	2,559	2,805
Contract liabilities	552	595
Other	14,798	25,328
	<u>\$ 24,866</u>	<u>\$ 37,072</u>

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

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

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

(In thousands)	2021				
	Gross goodwill at January 1	Cumulative impairment at January 1	Goodwill impairment	Foreign exchange and other	Balance at June 30
Pharmaceuticals					
CURNA	\$ 4,827	\$ (4,827)	\$ —	\$ —	\$ —
<i>Rayaldee</i>	93,418	—	—	(2,875)	90,543
FineTech	11,698	(11,698)	—	—	—
OPKO Biologics	139,784	—	—	—	139,784
OPKO Chile	4,505	—	—	(113)	4,392
OPKO Health Europe	8,086	—	—	(254)	7,832
OPKO Mexico	100	(100)	—	—	—
Transition Therapeutics	3,421	(3,421)	—	—	—
Diagnostics					
BioReference	434,809	—	—	—	434,809
OPKO Diagnostics	17,977	(17,977)	—	—	—
	<u>\$ 718,625</u>	<u>\$ (38,023)</u>	<u>\$ —</u>	<u>\$ (3,242)</u>	<u>\$ 677,360</u>

NOTE 6 INVESTMENTS
Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of June 30, 2021 and December 31, 2020:

(in thousands)	As of June 30, 2021		As of December 31, 2020	
	Investment Carrying Value	Underlying Equity in Net Assets	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	\$ 346	\$ 2,242	\$ 426	\$ 2,252
Variable interest entity, equity method	1,030	—	1,060	9
Equity securities	7,466		14,136	
Equity securities with no readily determinable fair value	35		35	
Warrants and options	68		74	
Total carrying value of investments	\$ 8,945		\$ 15,731	

Equity method investments

Our equity method investments consist of investments in Pharmsynthez (ownership 9%), Cocrystal Pharma, Inc. (“COCP”) (3%), Non-Invasive Monitoring Systems, Inc. (“NIMS”) (1%), Neovasc, Inc. (“Neovasc”) (1%), InCellDx, Inc. (“InCellDx”) (29%), BioCardia, Inc. (“BioCardia”) (1%), and Xenetic Biosciences, Inc. (“Xenetic”) (2%). The aggregate amount of assets, liabilities, and net losses of our equity method investees as of and for the six months ended June 30, 2021 were \$179.0 million, \$26.7 million, and \$5.9 million, respectively. The aggregate amount of assets, liabilities, and net losses of our equity method investees as of and for the year ended December 31, 2020 were \$90.9 million, \$28.4 million, and \$75.4 million, respectively. We have determined that we and/or our related parties can significantly influence control of our equity method investments through our board representation and/or voting power. Accordingly, we account for our investment in these entities under the equity method and record our proportionate share of their losses in Loss from investments in investees in our Condensed Consolidated Statement of Operations. The aggregate value of our equity method investments based on the quoted market prices of their respective shares of common stock and the number of shares held by us as of June 30, 2021 was \$7.1 million.

Investments in Equity Securities

Our equity securities consist of investments in Phio Pharmaceuticals (“Phio”) (ownership 0.01%), VBI Vaccines Inc. (“VBI”) (1%), ChromaDex Corporation (“ChromaDex”) (0.1%), and Eloxx Pharmaceuticals, Inc. (“Eloxx”) (2%). We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of these investments. Accordingly, we account for our investment in these entities as equity securities, and we record changes in the fair value of these investments in Other income (expense) each reporting period when they have readily determinable fair value. Equity securities without a readily determinable fair value are adjusted to fair value when there is an observable price change. Net gains and losses on our equity securities for the six months ended June 30, 2021, and 2020 were as follows:

(in thousands)	For the six months ended June 30	
	2021	2020
Equity Securities:		
Net gains and losses recognized during the period on equity securities	\$ 1,408	\$ 5,907
Less: Net gains and losses realized during the period on equity securities	(2,981)	—
Unrealized net gains and losses recognized during the period on equity securities still held at the reporting date	\$ (1,573)	\$ 5,907

Sales of investments

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

Warrants and options

In addition to our equity method investments and equity securities, we hold options to purchase 47 thousand additional shares of BioCardia, all of which were vested as of June 30, 2021 and December 31, 2020, and 33 thousand, 0.7 million, 40 thousand and 404 warrants to purchase shares of COCP, InCellDx, Inc., Xenetic, and Phio, respectively. We recorded the changes in the fair value of the options and warrants in Fair value changes of derivative instruments, net in our Condensed Consolidated Statement of Operations. We also recorded the fair value of the options and warrants in Investments, net in our Condensed Consolidated Balance Sheet. See further discussion of the Company's options and warrants in Note 9 and Note 10.

Investments in variable interest entities

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

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

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

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

We own 1,260,000 shares of Zebra Series A-2 Preferred Stock and 900,000 shares of Zebra restricted common stock (ownership 29% at June 30, 2021). Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Dr. Richard Lerner, M.D., a member of our Board of Directors, is a founder of Zebra and, along with Dr. Frost, serves as a member of Zebra's Board of Directors.

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

NOTE 7 DEBT

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

(In thousands)	June 30, 2021	December 31, 2020
2025 Notes	\$ 116,009	\$ 156,163
2023 Convertible Notes	64,139	62,776
2033 Senior Notes	3,050	3,050
JP Morgan Chase	—	7,057
Chilean and Spanish lines of credit	16,197	15,897
Current portion of notes payable	1,764	1,749
Long term portion of notes payable	4,517	4,513
Total	<u>\$ 205,676</u>	<u>\$ 251,205</u>
Balance sheet captions		
Convertible Notes	\$ 183,198	\$ 221,989
Current portion of lines of credit and notes payable	17,961	24,703
LT notes payable included in long-term liabilities	4,517	4,513
Total	<u>\$ 205,676</u>	<u>\$ 251,205</u>

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

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

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

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

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

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

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

In May 2021, we entered into exchange agreements with certain holders of the 2025 Notes pursuant to which the holders exchanged \$5.4 million in aggregate principal amount of the outstanding 2025 Notes for 19,051,270 shares of our Common Stock (the “Exchange”). We recorded an \$1.1 million non-cash loss related to the Exchange.

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

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

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

(In thousands)	2025 Senior Notes	Discount	Debt Issuance Cost	Total
Balance at December 31, 2020	\$ 200,000	\$ (39,537)	\$ (4,300)	\$ 156,163
Amortization of debt discount and debt issuance costs	—	3,617	394	4,011
Conversion	(55,420)	10,151	1,104	(44,165)
Balance at June 30, 2021	<u>\$ 144,580</u>	<u>\$ (25,769)</u>	<u>\$ (2,802)</u>	<u>\$ 116,009</u>

In February 2018, we issued a series of 5% Convertible Promissory Notes (the “2023 Convertible Notes”) in the aggregate principal amount of \$5.0 million. The 2023 Convertible Notes mature five years following the date of issuance. Each holder of a 2023 Convertible Note has the option, from time to time, to convert all or any portion of the outstanding principal balance of such 2023 Convertible Note, together with accrued and unpaid interest thereon, into shares of our Common Stock at a conversion price of \$5.00 per share. We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon, pro rata among the holders, upon no fewer than 30 days, and no more than 60 days, notice to the holders. The 2023 Convertible Notes contain customary events of default and representations and warranties of OPKO.

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

In January 2013, we entered into note purchase agreements with respect to the issuance and sale of our 8.0% Senior Notes due 2033 (the “2033 Senior Notes”) in a private placement exempt from registration under the Securities Act. We issued the 2033 Senior Notes on January 30, 2013. The 2033 Senior Notes, which totaled \$175.0 million in original principal amount,

bear interest at the rate of 3.0% per year, payable semiannually on February 1 and August 1 of each year. The 2033 Senior Notes mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change, as defined in the indenture governing the 2033 Senior Notes, subject to certain exceptions, the holders may require us to repurchase all or any portion of their 2033 Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the 2033 Senior Notes being repurchased, plus any accrued and unpaid interest to, but not including, the related fundamental change repurchase date.

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

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

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

In November 2015, BioReference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. ("CB"), as lender and administrative agent, as amended (the "Credit Agreement"). The Credit Agreement provides for a \$75.0 million secured revolving credit facility and includes a \$20.0 million sub-facility for swingline loans and a \$20.0 million sub-facility for the issuance of letters of credit. 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 June 30, 2021, \$64.3 million remained available for borrowing 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 0.25% of the lending commitments.

As of June 30, 2021 and December 31, 2020, no amount and \$7.1 million, respectively, was outstanding under the Credit Agreement.

The Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require BioReference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws and restrictions on the ability of BioReference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the Credit Agreement, notwithstanding the ability of BioReference to meet its debt service obligations. The Credit Agreement also

includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Credit Agreement and execution upon the collateral securing obligations under the Credit Agreement. Substantially all the assets of BioReference and its subsidiaries are restricted from sale, transfer, lease, disposal or distributions to the Company, subject to certain exceptions. As of June 30, 2021, BioReference and its subsidiaries had net assets of approximately \$1,095.7 million, which included goodwill of \$434.8 million and intangible assets of \$314.4 million.

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

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

Lender	Interest rate on borrowings at June 30, 2021	Credit line capacity	Balance Outstanding	
			June 30, 2021	December 31, 2020
JPMorgan Chase	3.75%	\$ 75,000	\$ —	\$ 7,057
Itau Bank	5.50%	2,887	2,887	2,353
Bank of Chile	6.60%	2,275	860	1,494
BICE Bank	5.50%	2,500	919	1,166
Scotiabank	5.50%	4,500	—	1,829
Santander Bank	5.50%	4,500	663	3,025
Security Bank	5.50%	2,797	2,797	262
Estado Bank	5.50%	4,700	2,161	2,127
BCI Bank	5.00%	2,645	2,645	—
Corpbanca	5.00%	3,265	3,265	3,641
Banco De Sabadell	1.75%	594	—	—
Santander Bank	1.82%	594	—	—
Total		\$ 106,257	\$ 16,197	\$ 22,954

At June 30, 2021 and December 31, 2020, the weighted average interest rate on our lines of credit was approximately 5.4% and 4.9%, respectively.

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

(In thousands)	June 30, 2021	December 31, 2020
Current portion of notes payable	\$ 1,764	\$ 1,749
Other long-term liabilities	4,517	4,513
Total	\$ 6,281	\$ 6,262

The notes and other debt mature at various dates ranging from 2020 through 2024, bearing variable interest rates from 0.7% up to 3.8%. The weighted average interest rate on the notes and other debt was 2.7% and 2.9% on June 30, 2021 and December 31, 2020. The notes are partially secured by our office space in Barcelona.

NOTE 8 ACCUMULATED OTHER COMPREHENSIVE LOSS

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

(In thousands)	Foreign currency translation
Balance at December 31, 2020	\$ (4,225)
Other comprehensive loss	(5,707)
Balance at June 30, 2021	\$ (9,932)

NOTE 9 FAIR VALUE MEASUREMENTS

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

As of June 30, 2021, we had equity securities (refer to Note 6), forward foreign currency exchange contracts for inventory purchases (refer to Note 10) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics and OPKO Renal that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with BioCardia, we record the related BioCardia options at fair value as well as the warrants from COCP, InCellDx, Xenetic and Phio.

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

Fair value measurements as of June 30, 2021				
(In thousands)	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Equity securities	\$ 7,466	\$ —	\$ —	\$ 7,466
Common stock options/warrants	—	68	—	68
Forward contracts	—	358	—	358
Total assets	\$ 7,466	\$ 426	\$ —	\$ 7,892
Liabilities:				
Contingent consideration	—	—	3,474	3,474
Total liabilities	\$ —	\$ —	\$ 3,474	\$ 3,474

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

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

(In thousands)	June 30, 2021				
	Carrying Value	Total Fair Value	Level 1	Level 2	Level 3
2025 Notes	\$ 116,009	\$ 188,902	\$ —	\$ 188,902	\$ —

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

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

(In thousands)	June 30, 2021	
		Contingent consideration
Balance at December 31, 2020	\$	5,695
Change in fair value:		
Included in results of operations		(1,059)
Payments		(1,162)
Balance at June 30, 2021	\$	3,474

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

Contingent consideration – We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to OPKO Diagnostics, CURNA and OPKO Renal transactions. As of June 30, 2021, of the \$3.5 million of contingent consideration, \$0.5 million was recorded in Accrued expenses and \$3.0 million was recorded in Other long-term liabilities. As of December 31, 2020, of the \$5.7 million of contingent consideration, \$1.2 million was recorded in Accrued expenses and \$4.5 million was recorded in Other long-term liabilities.

NOTE 10 DERIVATIVE CONTRACTS

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

<u>(In thousands)</u>	Balance Sheet Component	June 30, 2021	December 31, 2020
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	\$ 68	\$ 74
Forward contracts	Unrealized gains on forward contracts are recorded in Other current assets and prepaid expenses. Unrealized (losses) on forward contracts are recorded in Accrued expenses.	\$ 358	\$ (1,040)

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

To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At June 30, 2021 and December 31, 2020, our derivative financial instruments did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize the changes in Fair value of derivative instruments, net in our Condensed Consolidated Statement of Operations. The following table summarizes the losses and gains recorded for the three and six months ended June 30, 2021 and 2020:

<u>(In thousands)</u>	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Derivative gain (loss):				
Common Stock options/warrants	\$ (26)	\$ (7)	\$ (6)	\$ (69)
Forward contracts	(246)	(6)	(705)	677
Total	<u>\$ (272)</u>	<u>\$ (13)</u>	<u>\$ (711)</u>	<u>\$ 608</u>

NOTE 11 RELATED PARTY TRANSACTIONS

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

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

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

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

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

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

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

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

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

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost for out-of-pocket operating costs for the use of the airplane by Dr. Frost or Company executives for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive. For the three and six months ended June 30, 2021, we reimbursed approximately \$43 thousand for Company-related travel by Dr. Frost and other OPKO executives. For the three and six months ended June 30, 2020, we reimbursed approximately \$0 thousand and \$94 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives.

NOTE 12 COMMITMENTS AND CONTINGENCIES

In connection with our acquisitions of CURNA, OPKO Diagnostics and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of June 30, 2021, we recorded \$3.5 million as contingent consideration, with \$0.5 million recorded within Accrued expenses and \$3.0 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 5 and Note 17.

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

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

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

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

From time to time, we may receive inquiries, document requests, CIDs or subpoenas from the Department of Justice, OCR, CMS, various payors and fiscal intermediaries, and other state and federal regulators regarding investigations, audits and reviews. In addition to the matters discussed in this note, we are currently responding to CIDs, subpoenas, payor audits, and document requests for various matters relating to our laboratory operations. Some pending or threatened proceedings against us may involve potentially substantial amounts as well as the possibility of civil, criminal, or administrative fines, penalties, or other sanctions, which could be material. Settlements of suits involving the types of issues that we routinely confront may require monetary payments as well as corporate integrity agreements. Additionally, qui tam or "whistleblower" actions initiated under the civil False Claims Act may be pending but placed under seal by the court to comply with the False Claims Act's requirements for filing such suits. Also, from time to time, we may detect issues of non-compliance with federal healthcare laws pertaining to claims submission and reimbursement practices and/or financial relationships with physicians, among other things. We may avail ourselves of various mechanisms to address these issues, including participation in voluntary disclosure protocols. Participating in voluntary disclosure protocols can have the potential for significant settlement obligations or even enforcement action. The Company generally has cooperated, and intends to continue to cooperate, with appropriate regulatory authorities as and when investigations, audits and inquiries arise.

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

At June 30, 2021, we were committed to make future purchases for inventory and other items in 2021 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating approximately \$135.5 million.

NOTE 13 REVENUE RECOGNITION

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

Revenue from services

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

The following are descriptions of our payors for laboratory services:

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

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

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

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

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

The complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as considerations unique to Medicare and Medicaid programs, require us to estimate the potential for retroactive adjustments as an element of variable consideration in the recognition of revenue in the period the related services are rendered. Actual amounts are adjusted in the period those adjustments become known. For the six months ended June 30, 2021 and June 30 2020, positive revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of \$28.5 million and \$0.2 million were recognized, respectively. Revenue adjustments for the six months ended June 30, 2021 were primarily due to an improvement in COVID-19 test reimbursement estimates.

Third-party payors, including government programs, may decide to deny payment or recoup payments for testing they contend were improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. Our revenues may be subject to retroactive adjustment as a result of these factors among others, including without limitation, differing interpretations of billing and coding guidance and changes by government agencies and payors in interpretations, requirements, and “conditions of participation” in various programs. We have processed requests for recoupment from third-party payors in the ordinary course of our business, and it is likely that we will continue to do so in the future. If a third-party payor denies payment for testing or recoups money from us in a later period, reimbursement for our testing could decline.

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

Settlements with third-party payors for retroactive adjustments due to audits, reviews or investigations are also considered variable consideration and are included in the determination of the estimated transaction price for providing services. These settlements are estimated based on the terms of the payment agreement with the payor, correspondence from the payor and our historical settlement activity, including an assessment of the probability a significant reversal of cumulative revenue recognized will occur when the uncertainty is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews, and investigations. As of June 30, 2021 and December 31, 2020, we had liabilities of approximately \$9.5 million and \$14.9 million, respectively, within Accrued expenses and Other long-term liabilities related to reimbursements for payor overpayments.

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

(In thousands)	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Healthcare insurers	\$ 109,084	\$ 84,082	\$ 273,913	\$ 183,232
Government payers	57,611	15,886	131,269	42,784
Client payers	225,936	141,090	488,845	180,191
Patients	4,566	9,913	10,122	15,604
Total	\$ 397,197	\$ 250,971	\$ 904,149	\$ 421,811

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.

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

We recognize revenue for shipments of *Royaldee* at the time of delivery to customers after estimating Sales Deductions and product returns as elements of variable consideration utilizing historical information and market research projections. For the three and six months ended June 30, 2021, we recognized \$5.0 million and \$8.6 million, respectively, in net product revenue from sales of *Royaldee*. For the three and six months ended June 30, 2020, we recognized \$6.6 million and \$18.6 million, respectively, in net product revenue from sales of *Royaldee*.

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

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at March 31, 2021	\$ 1,693	\$ 6,209	\$ 3,487	\$ 11,389
Provision related to current period sales	3,724	7,061	322	11,107
Credits or payments made	(3,716)	(5,684)	(485)	(9,885)
Balance at June 30, 2021	\$ 1,701	\$ 7,586	\$ 3,324	\$ 12,611
Total gross <i>Royaldee</i> sales				\$ 16,122
Provision for <i>Royaldee</i> sales allowances and accruals as a percentage of gross <i>Royaldee</i> sales				69%

(In thousands)	Chargebacks, discounts, rebates and fees	Governmental	Returns	Total
Balance at December 31, 2020	\$ 2,332	\$ 5,812	\$ 3,593	\$ 11,737
Provision related to current period sales	7,539	12,755	635	20,929
Credits or payments made	(8,170)	(10,981)	(904)	(20,055)
Balance at June 30, 2021	\$ 1,701	\$ 7,586	\$ 3,324	\$ 12,611
Total gross <i>Royaldee</i> sales				\$ 31,767
Provision for <i>Royaldee</i> sales allowances and accruals as a percentage of gross <i>Royaldee</i> sales				66%

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 six months ended June 30, 2021, revenue from transfer of intellectual property principally reflects \$2.8 million and \$5.6 million of revenue, respectively, related to the Pfizer Transaction (as defined below) and a \$5.0 million non-refundable upfront payment we have received under the Nicoya Agreement (as defined below). For the three and six months ended June 30, 2020, revenue from transfer of intellectual property principally reflects \$13.9 million and \$22.7 million of revenue, respectively, related to the Pfizer Transaction. In addition, revenue from the transfer of intellectual property and other for the three and six months ended June 30, 2020 includes a \$6.2 million grant received by BioReference from the CARES Act. Refer to Note 14 for discussion of the Pfizer Transaction.

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

<i>(In thousands)</i>	
Balance at December 31, 2020	\$ 16,378
Balance at June 30, 2021	8,952
Revenue recognized in the period from:	
Amounts included in contracts liability at the beginning of the period	7,425

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

NOTE 14 STRATEGIC ALLIANCES

NICOYA Macau Limited

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

EirGen has received an initial upfront payment of \$5 million and is eligible to receive an additional \$5 million upon the first to occur of (A) a predetermined milestone and (B) the first anniversary of the effective date. EirGen is also eligible to receive up to an additional aggregate amount of \$115 million upon the achievement of certain development, regulatory and sales-based milestones by Nicoya for the Nicoya Product in the Nicoya Territory. EirGen will also receive tiered, double digit royalty payments at rates in the low double digits on net product sales within the Nicoya Territory and in the Nicoya Field.

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

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

Japan Tobacco Inc.

On October 12, 2017, EirGen 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 *Royaldee* 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").

On May 17, 2021, JT delivered to the Company a notice of termination of the JT Agreement pursuant to Section 16.1(a) thereof, which permits termination by JT for any reason, indicating its decision to discontinue development of the product for the Japanese market based on a comprehensive review of its development pipeline. The termination of the JT Agreement became effective shortly thereafter upon Vifor Fresenius Medical Care Renal Pharma Ltd's ("VMCRP") assumption of the JT Territory.

Vifor Fresenius Medical Care Renal Pharma Ltd

In May 2016, EirGen and VMCRP entered into a Development and License Agreement (the "VMCRP Agreement") for the development and commercialization of *Royaldee* (the "Product") worldwide, except for (i) the U.S., (ii) any country in Central America or South America (including Mexico), (iii) Russia, (iv) China, (v) South Korea, (vi) Ukraine, (vii) Belorussia, (viii) Azerbaijan, (ix) Kazakhstan, (x) Taiwan (xi) the Middle East, and (xii) all countries of Africa (the "VMCRP Territory"), as amended. The license to VMCRP potentially covers all therapeutic and prophylactic uses of the Product in human patients (the "VMCRP 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 "VMCRP Initial Indication").

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

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

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

In connection with the VMCRP Agreement, the parties entered into a letter agreement pursuant to which EirGen granted to VMCRP 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, VMCRP 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. VMCRP 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, VFMCRCR has not exercised its option.

Payments received for regulatory milestones and sales milestones are non-refundable. The regulatory milestones are payable if and when VFMCRCR 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 Somatrogen (hGH-CTP) for the treatment of growth hormone deficiency (“GHD”) in adults and children, as well as for the treatment of growth failure in children born small for gestational age (the “Pfizer Transaction”).

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

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

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

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

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

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

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

Pharmsynthez

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

Other

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

NOTE 15 SEGMENTS

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

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

(In thousands)	For the three months ended June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Revenue from services:				
Pharmaceutical	\$ —	\$ —	\$ —	\$ —
Diagnostics	397,197	250,971	904,149	421,811
Corporate	—	—	—	—
	<u>\$ 397,197</u>	<u>\$ 250,971</u>	<u>\$ 904,149</u>	<u>\$ 421,811</u>
Revenue from products:				
Pharmaceutical	\$ 35,663	\$ 29,356	\$ 69,608	\$ 60,430
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	<u>\$ 35,663</u>	<u>\$ 29,356</u>	<u>\$ 69,608</u>	<u>\$ 60,430</u>
Revenue from transfer of intellectual property and other:				
Pharmaceutical	\$ 9,548	\$ 14,686	\$ 13,816	\$ 24,239
Diagnostics	—	6,194	—	6,194
Corporate	—	—	—	—
	<u>\$ 9,548</u>	<u>\$ 20,880</u>	<u>\$ 13,816</u>	<u>\$ 30,433</u>
Operating income (loss):				
Pharmaceutical	\$ (13,710)	\$ (5,996)	\$ (32,868)	\$ (20,121)
Diagnostics	30,000	40,935	97,014	22,803
Corporate	(10,719)	(7,760)	(20,138)	(16,263)
	<u>\$ 5,571</u>	<u>\$ 27,179</u>	<u>\$ 44,008</u>	<u>\$ (13,581)</u>
Depreciation and amortization:				
Pharmaceutical	\$ 7,007	\$ 7,119	\$ 14,420	\$ 14,240
Diagnostics	13,566	15,147	26,141	30,019
Corporate	—	—	—	59
	<u>\$ 20,573</u>	<u>\$ 22,266</u>	<u>\$ 40,561</u>	<u>\$ 44,318</u>
Loss from investment in investees:				
Pharmaceutical	\$ (67)	\$ (189)	\$ (110)	\$ (323)
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	<u>\$ (67)</u>	<u>\$ (189)</u>	<u>\$ (110)</u>	<u>\$ (323)</u>
Revenues:				
United States	\$ 402,291	\$ 265,890	\$ 915,163	\$ 446,761
Ireland	12,088	16,847	19,218	28,749
Chile	18,657	11,152	32,809	22,002
Spain	5,437	4,136	11,356	8,292
Israel	724	1,183	3,235	2,890
Mexico	3,039	1,866	5,457	3,708
Other	172	133	335	272
	<u>\$ 442,408</u>	<u>\$ 301,207</u>	<u>\$ 987,573</u>	<u>\$ 512,674</u>

(In thousands)	June 30, 2021	December 31, 2020
Assets:		
Pharmaceutical	\$ 1,158,213	\$ 1,176,245
Diagnostics	1,227,256	1,268,738
Corporate	36,181	28,080
	<u>\$ 2,421,650</u>	<u>\$ 2,473,063</u>
Goodwill:		
Pharmaceutical	\$ 242,551	\$ 245,793
Diagnostics	434,809	434,809
Corporate	—	—
	<u>\$ 677,360</u>	<u>\$ 680,602</u>

No customer represented more than 10% of our total consolidated revenue during the six months ended June 30, 2021 and 2020. As of June 30, 2021 and December 31, 2020, no customer represented more than 10% of our accounts receivable balance.

NOTE 16 LEASES

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

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

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

(in thousands)	Classification on the Balance Sheet	June 30, 2021	December 31, 2020
Assets			
Operating lease assets	Operating lease right-of-use assets	\$ 36,349	\$ 37,735
Finance lease assets	Property, plant and equipment, net	4,643	5,258
Liabilities			
Current			
Operating lease liabilities	Current maturities of operating leases	10,102	9,028
Accrued expenses	Current maturities of finance leases	2,084	2,453
Long-term			
Operating lease liabilities	Operating lease liabilities	30,605	29,760
Other long-term liabilities	Finance lease liabilities	\$ 2,559	\$ 2,805
Weighted average remaining lease term			
Operating leases		5.8 years	5.4 years
Finance leases		2.6 years	2.3 years
Weighted average discount rate			
Operating leases		5.7 %	5.8 %
Finance leases		5.3 %	3.6 %

The following table reconciles the undiscounted future minimum lease payments (displayed by year and in the aggregate) under noncancelable operating leases with terms of more than one year to the total operating lease liabilities recognized on our Condensed Consolidated Balance Sheet as of June 30, 2021:

(in thousands)	Operating	Finance
July 1, 2021 through December 31, 2021	\$ 4,535	\$ 1,293
2022	10,995	1,648
2023	7,722	1,038
2024	5,700	697
2025	3,726	215
Thereafter	16,367	—
Total undiscounted future minimum lease payments	49,045	4,891
Less: Difference between lease payments and discounted lease liabilities	8,338	248
Total lease liabilities	\$ 40,707	\$ 4,643

Expense under operating leases and finance leases was \$9.1 million and \$1.1 million, respectively, for the three and six months ended June 30, 2021, which includes \$1.4 million of variable lease costs. Expense under operating leases and finance leases was \$9.7 million and \$1.2 million, respectively, for the three and six months ended June 30, 2020, which includes \$1.6 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)	For the six months ended June 30,	
	2021	2020
Operating cash out flows from operating leases	\$ 6,484	\$ 9,804
Operating cash out flows from finance leases	45	86
Financing cash out flows from finance leases	769	1,026
Total	\$ 7,298	\$ 10,916

NOTE 17 SUBSEQUENT EVENTS

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

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

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

In June 2021, we announced that EirGen entered into a definitive agreement to sell one of its facilities in Waterford, Ireland to Horizon Therapeutics plc for \$65 million in cash less certain assumed and accrued liabilities relating to transferred employees. The facility previously housed EirGen’s sterile-fill-finish business and is no longer a core component of our ongoing operations and business strategy. The transaction closed on July 19, 2021.

We have reviewed all subsequent events and transactions that occurred after the date of our June 30, 2021 Condensed Consolidated Balance Sheet, 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 together with our audited consolidated financial statements, related notes, and other information contained in our Annual Report on Form 10-K for the year ended December 31, 2020 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part I, Item 1A of the Form 10-K and as described from time to time in our other filings with the Securities and Exchange Commission. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes BioReference Laboratories, Inc. ("BioReference"), one of the nation's largest full service laboratories with a core genetic testing business and an almost 300-person sales and marketing team to drive growth and leverage new products, including the *4Kscore* test. Our pharmaceutical business features *Royaldee*, a U.S. Food and Drug Administration ("FDA") approved treatment for secondary hyperparathyroidism ("SHPT") in adults with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency (launched in November 2016) and a pipeline of products in various stages of development. Our leading product in development is Somatrogen (hGH-CTP), a once-weekly human growth hormone for which we have partnered with Pfizer, Inc. ("Pfizer") and successfully completed a phase 3 study in August 2019, and for which the FDA has accepted the initial Biologics License Application ("BLA") for filing. We have also submitted a New Drug Application (an "NDA") with the Ministry of Health, Labour and Welfare in Japan and a Marketing Authorization Application with the European Medicines Agency. We are incorporated in Delaware, and our principal executive offices are located in leased offices in Miami, Florida.

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

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

RECENT DEVELOPMENTS

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

We received an initial upfront payment of \$1.5 million and 3,373,008 shares of CAMP4's Series A Prime Preferred Stock ("Preferred Stock"), which equates to approximately 5% of the outstanding shares of CAMP4, and are eligible to receive up to \$3.5 million in development milestone payments for Dravet syndrome products, and \$4 million for non-Dravet syndrome products, as well as sales milestones of up to \$90 million for Dravet syndrome products and up to \$90 million for non-Dravet syndrome products. We may also receive double digit royalty payments on the net sales of royalty bearing products, subject to adjustment. In addition, upon achievement of certain development milestones, we will be eligible to receive equity consideration of up to 5,782,299 shares of Preferred Stock in connection with Dravet syndrome products and up to 1,082,248 shares of Preferred stock in connection with non-Dravet syndrome products.

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

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

EirGen received an initial upfront payment of \$5 million and is eligible to receive an additional \$5 million upon the first to occur of (A) a certain predetermined milestone, or (B) the first anniversary of the effective date. EirGen is also eligible to receive up to an additional aggregate amount of \$115 million upon the achievement of certain development, regulatory and sales-based milestones by Nicoya for the Nicoya Product in the Nicoya Territory. EirGen will also receive tiered, double digit royalty payments at rates in the low double digits on net product sales within the Nicoya Territory and in the Nicoya Field.

In June 2021, we announced that EirGen entered into a definitive agreement to sell one of its facilities in Waterford, Ireland to Horizon Therapeutics plc for \$65 million in cash less certain assumed and accrued liabilities relating to transferred employees. The facility houses EirGen's sterile-fill-finish business and is no longer a core component of our ongoing operations and business strategy. The transaction closed in the third quarter of 2021.

In June 2021, we terminated the credit agreement with an affiliate of Dr. Frost, pursuant to which the lender committed to provide us with an unsecured line of credit in the amount of \$100 million was terminated and as of June 30, 2021, no amount was outstanding thereunder.

Effective May 23, 2021, we entered into an amendment to our agreement with VFMCRP for the development and commercialization of *Royaldee*, pursuant to which the parties agreed to include Japan as part of the VFMCRP Territory.

On May 17, 2021, JT delivered to the Company a notice of termination of the JT Agreement pursuant to Section 16.1(a) thereof, which permits termination by JT for any reason, indicating its decision to discontinue development of *Royaldee* for the Japanese market based on a comprehensive review of its development pipeline.

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

RESULTS OF OPERATIONS

Impact of COVID-19

As the disease caused by SARS-CoV-2, a novel strain of coronavirus, COVID-19 continues to spread and severely impact the U.S. economy and economies of other countries around the world, we are committed to being a part of the coordinated public and private sector response to this unprecedented challenge. In response to the COVID-19 pandemic, BioReference is providing COVID-19 solutions, including diagnostic molecular testing and serology antibody testing, to meet the testing needs of its numerous customer verticals, including physicians, health systems, long-term care facilities, governments, schools, employers, professional sports teams and entertainment venues, as well as the general public through relationships with retail pharmacy chains.

Revenue from services for the six months ended June 30, 2021 increased by \$482.3 million as compared to 2020 due to COVID-19 testing volumes; however we are unable to predict how long the demand will continue for our COVID-19 related testing, or whether pricing and reimbursement policies for testing will sustain, and accordingly, the sustainability of our COVID-19 testing volumes is uncertain. Additionally, beginning in March 2020, BioReference experienced a decline in testing volumes due to the COVID-19 pandemic; however as stay at home orders and other restrictions have been lifted, we have seen our routine clinical and genomic testing volumes trending towards normalization with prior periods. Should stay at home orders or other restrictions be reenacted, we could see our routine testing levels decline. Excluding COVID-19 test volumes, for the six months ended June 30, 2021, genomic and routine clinical test volume increased 39.0% and 13.4% as compared to volumes for the six months ended June 30, 2020. Additionally, sales of *Rayaldee* have not increased in accordance with its expected growth trajectory as a result of challenges in onboarding new patients due to the COVID-19 pandemic. Federal, state and local governmental policies and initiatives designed to reduce the transmission of COVID-19 have resulted in, among other things, a significant reduction in physician office visits, the cancellation of elective medical procedures, customers closing or severely curtailing their operations (voluntarily or in response to government orders), and the adoption of work-from-home or shelter-in-place policies. We also continue to see a substantial need for COVID-19 testing by our existing clients and expect new clients as infections for the virus continue.

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

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

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

Since the pandemic began in the U.S., we have invested in testing capabilities and infrastructure to meet demand for our molecular and antibody testing for COVID-19.

Three vaccines for COVID-19 have received approval or emergency authorization and have had increasingly widespread acceptance. However, we believe that, based on our experience with the pandemic, the high medical need for efficient and

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

FOR THE THREE MONTHS ENDED JUNE 30, 2021 AND 2020

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

(In thousands)	For the three months ended June 30,			
	2021	2020	Change	% Change
Revenues:				
Revenue from services	\$ 397,197	\$ 250,971	\$ 146,226	58 %
Revenue from products	35,663	29,356	6,307	21 %
Revenue from transfer of intellectual property and other	9,548	20,880	(11,332)	(54)%
Total revenues	442,408	301,207	141,201	47 %
Costs and expenses:				
Cost of revenue	292,908	162,651	130,257	80 %
Selling, general and administrative	113,236	77,721	35,515	46 %
Research and development	18,222	17,608	614	3 %
Contingent Consideration	(103)	1,111	(1,214)	(109)%
Amortization of intangible assets	12,574	14,937	(2,363)	(16)%
Total costs and expenses	436,837	274,028	162,809	59 %
Income (loss) from operations	5,571	27,179	(21,608)	(80)%

Diagnostics

(In thousands)	For the three months ended June 30,			
	2021	2020	Change	% Change
Revenues				
Revenue from services	\$ 397,197	\$ 250,971	\$ 146,226	58 %
Revenue from transfer of intellectual property and other	—	6,194	(6,194)	(100)%
Total revenues	397,197	257,165	140,032	54 %
Costs and expenses:				
Cost of revenue	267,806	144,783	123,023	85 %
Selling, general and administrative	87,809	57,712	30,097	52 %
Research and development	4,023	3,785	238	6 %
Contingent Consideration	—	35	(35)	(100)%
Amortization of intangible assets	7,559	9,915	(2,356)	(24)%
Total costs and expenses	367,197	216,230	150,967	70 %
Income (loss) from operations	30,000	40,935	(10,935)	(27)%

Revenue. Revenue from services for the three months ended June 30, 2021 increased by approximately \$146.2 million compared to the three months ended June 30, 2020. BioReference recognized an increase in revenue for the three months ended June 30, 2021 compared to the three months ended June 30, 2020 due to an increase in clinical test volume and genomic test

volume of \$33.9 million and \$13.1 million, respectively. This was partially offset by the negative impact of a reduction in clinical test reimbursement and genomic test reimbursement of \$5.3 million and \$7.1 million, respectively.

BioReference also recognized an increase in revenue for the three months ended June 30, 2021 compared to the three months ended June 30, 2020 due to an increase in COVID-19 testing volume and improvement in COVID-19 test reimbursement of \$35.4 million and \$70.1 million, respectively. BioReference performed 2.8 million diagnostic molecular tests for COVID-19 and 0.1 million serology antibody tests during the three months ended June 30, 2021, which represented 56.4% of total volume for that period. In comparison, the three months ended June 30, 2020 included 2.2 million molecular tests for COVID-19 and 0.3 million serology antibody tests.

Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as considerations unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when estimating variable consideration in the recognition of revenue in the period the related services are rendered. For the three months ended June 30, 2021 and 2020, positive revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of \$0.5 million and \$9.0 million were recognized, respectively. Revenue adjustments for the three months ended June 30, 2021 were primarily due to an improvement in COVID-19 test reimbursement estimates.

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

(In thousands)	Three months ended June 30,	
	2021	2020
Healthcare insurers	\$ 109,084	\$ 84,082
Government payers	57,611	15,886
Client payers	225,936	141,090
Patients	4,566	9,913
Total	\$ 397,197	\$ 250,971

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

Revenue from the transfer of intellectual property and other for the three months ended June 30, 2020 are the result of grants received under the CARES Act totaling \$6.2 million.

Cost of revenue. Cost of revenue for the three months ended June 30, 2021 increased \$123.0 million compared to the three months ended June 30, 2020. Cost of revenue increased primarily due to labor and material costs for COVID-19 testing and the significant volume of tests performed during the three months ended June 30, 2021. Cost of revenue for the three months ended June 30, 2021 also increased due to changes in the product mix of items sold during the period.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended June 30, 2021 and 2020 were \$87.8 million and \$57.7 million, respectively. Selling, general and administrative expenses in our diagnostics segment increased primarily due to higher variable billing and compensation costs from an increase in volume and collections during the three months ended June 30, 2021, and in marketing costs and other administrative costs directly associated with COVID-19 testing volumes. Selling, general and administrative expenses for the three months ended June 30, 2021 also include \$6.1 million of expense incurred in connection with certain legal matters.

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

Research and Development Expenses	Three months ended June 30,	
	2021	2020
External expenses:		
PMA studies	\$ 31	\$ 57
Research and development employee-related expenses	2,742	2,163
Other internal research and development expenses	1,250	1,565
Total research and development expenses	\$ 4,023	\$ 3,785

Research and development expenses for the three months ended June 30, 2021 were consistent with research and development expenses for the three months ended June 30, 2020. Research and development expenses for the three months ended June 30, 2021 are primarily related to the development of clinical and genomics testing services.

Contingent consideration. Contingent consideration for the three months ended June 30, 2021 and 2020 was \$0.0 thousand and \$35.0 thousand of expense, respectively. Contingent consideration for the three months ended June 30, 2020 was attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Diagnostics, and potential amounts payable to former stockholders of OPKO Diagnostics in connection therewith pursuant to our acquisition agreement in October 2011.

Amortization of intangible assets. Amortization of intangible assets was \$7.6 million and \$9.9 million, respectively, for the three months ended June 30, 2021 and 2020. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization expense declined during the three months ended June 30, 2021 due to acquired intangible assets becoming fully amortized.

Pharmaceuticals

(In thousands)	For the three months ended June 30,			
	2021	2020	Change	% Change
Revenues:				
Revenue from products	\$ 35,663	\$ 29,356	\$ 6,307	21 %
Revenue from transfer of intellectual property and other	9,548	14,686	(5,138)	(35)%
Total revenues	45,211	44,042	1,169	3 %
Costs and expenses:				
Cost of revenue	25,111	17,882	7,229	40 %
Selling, general and administrative	14,120	12,007	2,113	18 %
Research and development	14,778	14,051	727	5 %
Contingent Consideration	(103)	1,076	(1,179)	(110)%
Amortization of intangible assets	5,015	5,022	(7)	— %
Total costs and expenses	58,921	50,038	8,883	18 %
Loss from operations	(13,710)	(5,996)	(7,714)	129 %

Revenue. The increase in revenue from products for the three months ended June 30, 2021 compared to the three months ended June 30, 2020 was primarily attributable to an increase in sales at most of our international operating companies. Revenue from sales of *Royaldee* for the three months ended June 30, 2021 and 2020 was \$5.0 million and \$8.6 million, respectively. Sales of *Royaldee* have been negatively impacted as a result of challenges in onboarding new patients due to the COVID-19 pandemic. Revenue from transfer of intellectual property for the three months ended June 30, 2021 and 2020 principally reflected \$2.8 million and \$13.9 million, respectively, of revenue related to the Pfizer Transaction. Revenue from transfer of intellectual property for the three months ended June 30, 2021 also includes a \$5.0 million non-refundable upfront payment we will receive under the license agreement with Nicoya Agreement.

Cost of revenue. Cost of revenue for the three months ended June 30, 2021 increased \$7.2 million compared to the three months ended June 30, 2020 primarily due to an increase in inventory and material costs at most of our international operating companies, which was due to the increase in sales at our international operating companies. This was partially offset by a decrease in sales of *Royaldee* for the three months ended June 30, 2021 compared to the three months ended June 30, 2020.

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended June 30, 2021 and 2020 were \$14.1 million and \$12.0 million, respectively. The increase in selling, general and administrative expenses was primarily due to an increase in selling, general and administrative expenses for most of our international operating companies primarily due to higher variable costs from an increase in sales volume during the three months ended June 30, 2021. Selling, general and administrative expenses for the pharmaceutical segment for the three months ended June 30, 2021 and 2020 included equity-based compensation expense of \$0.4 million and \$0.2 million, respectively.

Research and development expenses. Research and development expenses for the three months ended June 30, 2021 and 2020 were \$14.8 million and \$14.1 million, respectively. Research and development expenses include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and premarket approval for diagnostics tests, if any. Internal expenses include employee-related expenses such as salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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

Research and Development Expenses	Three months ended June 30,	
	2021	2020
External expenses:		
Manufacturing expense for biological products	\$ 912	\$ (309)
Phase III studies	2,660	2,297
Post-marketing studies	22	282
Earlier-stage programs	4,841	3,964
Research and development employee-related expenses	4,927	4,886
Other internal research and development expenses	1,430	2,931
Third-party grants and funding from collaboration agreements	(14)	—
Total research and development expenses	\$ 14,778	\$ 14,051

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

Contingent consideration. Contingent consideration for the three months ended June 30, 2021 and 2020 was \$0.1 million reversal of expense and \$1.1 million of expense, respectively. Contingent consideration for the three months ended June 30, 2021 was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal and OPKO CURNA, and potential amounts payable to former stockholders of OPKO Renal and OPKO CURNA in connection therewith, pursuant to our acquisition agreements in March 2013 and January 2011, respectively. Contingent consideration for the three months ended June 30, 2020 was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal, and potential amounts payable to former stockholders of OPKO Renal.

Amortization of intangible assets. Amortization of intangible assets was \$5.0 million and \$5.0 million, respectively, for the three months ended June 30, 2021 and 2020. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Our indefinite lived IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the FDA, the IPR&D assets will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Corporate

(In thousands)	For the three months ended June 30,			
	2021	2020	Change	% Change
Costs and expenses:				
Cost of revenue	\$ (9)	\$ (14)	\$ 5	(36)%
Selling, general and administrative	11,307	8,002	3,305	41 %
Research and development	(579)	(228)	(351)	154 %
Total costs and expenses	10,719	7,760	2,959	38 %
Loss from operations	(10,719)	(7,760)	(2,959)	38 %

Operating loss for our unallocated corporate operations for the three months ended June 30, 2021 and 2020 was \$10.7 million and \$7.8 million, respectively, and principally reflects general and administrative expenses incurred in connection with our corporate operations. The increase in operating loss for the three months ended June 30, 2021 was primarily attributable to an increase in legal and accounting fees incurred for the three months ended June 30, 2021, compared to the three months ended June 30, 2020.

Other

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

Interest expense. Interest expense for the three months ended June 30, 2021 and 2020 was \$4.9 million and \$5.5 million, respectively. Interest expense was principally related to interest incurred on the 2025 Notes, the 2023 Convertible Notes, the 2033 Senior Notes, and BioReference's outstanding debt under the Credit Agreement.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended June 30, 2021 and 2020, was \$272 thousand and \$13 thousand of expense, respectively. Derivative expense for the three months ended June 30, 2021, was principally related to the change in fair value on foreign currency forward exchange contracts at OPKO Chile.

Other income (expense), net. Other income (expense), net for the three months ended June 30, 2021 and 2020, was \$11.8 million of expense and \$18.2 million of income, respectively. Other expense for the three months ended June 30, 2021 primarily consisted of a \$11.1 million non-cash loss related to the exchange of \$55.4 million of the outstanding 2025 Notes for 19,051,270 shares of our Common Stock. Other income for the three months ended June 30, 2020 primarily consisted of net unrealized gains recognized during the period on our investment in VBI.

Income tax provision. Our income tax provision for the three months ended June 30, 2021 and 2020 was \$4.8 million and \$6.0 million, respectively, and reflects quarterly results using our expected effective tax rate. For the three months ended June 30, 2021, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in certain early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report net losses. Loss from investments in investees was \$0.1 million and \$0.2 million for the three months ended June 30, 2021 and 2020, respectively.

FOR THE SIX MONTHS ENDED JUNE 30, 2021 AND 2020

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

(In thousands)	For the six months ended June 30,		Change	% Change
	2021	2020		
Revenues:				
Revenue from services	\$ 904,149	\$ 421,811	\$ 482,338	114 %
Revenue from products	69,608	60,430	9,178	15 %
Revenue from transfer of intellectual property and other	13,816	30,433	(16,617)	(55)%
Total revenues	987,573	512,674	474,899	93 %
Costs and expenses:				
Cost of revenue	656,414	302,909	353,505	117 %
Selling, general and administrative	225,522	153,852	71,670	47 %
Research and development	37,537	39,369	(1,832)	(5)%
Contingent Consideration	(1,059)	251	(1,310)	(522)%
Amortization of intangible assets	25,151	29,874	(4,723)	(16)%
Total costs and expenses	943,565	526,255	417,310	79 %
Income (loss) from operations	44,008	(13,581)	57,589	(424)%

Diagnostics

(In thousands)	For the six months ended June 30,		Change	% Change
	2021	2020		
Revenues				
Revenue from services	\$ 904,149	\$ 421,811	\$ 482,338	114 %
Revenue from transfer of intellectual property and other	—	6,194	(6,194)	(100)%
Total revenues	904,149	428,005	476,144	111 %
Costs and expenses:				
Cost of revenue	607,233	267,689	339,544	127 %
Selling, general and administrative	177,127	110,436	66,691	60 %
Research and development	7,654	7,178	476	7 %
Contingent Consideration	—	68	(68)	(100)%
Amortization of intangible assets	15,121	19,831	(4,710)	(24)%
Total costs and expenses	807,135	405,202	401,933	99 %
Income from operations	97,014	22,803	74,211	325 %

Revenue. Revenue from services for the six months ended June 30, 2021 increased by approximately \$482.3 million compared to the six months ended June 30, 2020. BioReference recognized an increase in revenue for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 due to an improvement in clinical test reimbursement, and an increase in clinical test volume and genomic test volume of \$14.0 million, \$28.7 million and \$14.7 million, respectively. This was partially offset by the negative impact of a reduction in genomic test reimbursement of \$17.6 million.

BioReference also recognized an increase in revenue for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 due to an increase in COVID-19 testing volume and improvement in COVID-19 test reimbursement of \$278.7 million and \$157.9 million, respectively. BioReference performed 6.9 million diagnostic molecular tests for COVID-19 and 0.3 million serology antibody tests during the six months ended June 30, 2021, which represented 61.6% of total volume for that period. In comparison, the six months ended June 30, 2020 included 2.3 million molecular tests for COVID-19 and 0.3 million serology antibody tests.

Estimated collection amounts are subject to the complexities and ambiguities of billing, reimbursement regulations and claims processing, as well as considerations unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when estimating variable consideration in the recognition of revenue in the period the

related services are rendered. For the six months ended June 30, 2021 and 2020, positive revenue adjustments due to changes in estimates of implicit price concessions for performance obligations satisfied in prior periods of \$28.5 million and \$0.2 million were recognized, respectively. Revenue adjustments for the six months ended June 30, 2021 were primarily due to an improvement in COVID-19 test reimbursement estimates.

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

(In thousands)	Six months ended June 30,	
	2021	2020
Healthcare insurers	\$ 273,913	\$ 183,232
Government payers	131,269	42,784
Client payers	488,845	180,191
Patients	10,122	15,604
Total	<u>\$ 904,149</u>	<u>\$ 421,811</u>

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

Revenue from the transfer of intellectual property and other for the six months ended June 30, 2020 are the result of grants received under the CARES Act totaling \$6.2 million.

Cost of revenue. Cost of revenue for the six months ended June 30, 2021 increased \$339.5 million compared to the six months ended June 30, 2020. Cost of revenue increased primarily due to labor and material costs for COVID-19 testing and the significant volume of tests performed during the six months ended June 30, 2021. Cost of revenue for the six months ended June 30, 2021 also increased due to changes in the product mix of items sold during the period.

Selling, general and administrative expenses. Selling, general and administrative expenses for the six months ended June 30, 2021 and 2020 were \$177.1 million and \$110.4 million, respectively. Selling, general and administrative expenses in our diagnostics segment increased primarily due to higher variable billing and compensation costs from an increase in volume and collections during the six months ended June 30, 2021, and in marketing costs and other administrative costs directly associated with COVID-19 testing volumes. Selling, general and administrative expenses for the six months ended June 30, 2021 also include \$6.1 million of expense incurred in connection with certain legal matters. As a percentage of net revenue, selling, general and administrative expenses for the diagnostic segment decreased to 20% from 26% for the six months ended June 30, 2021 and 2020, respectively, as a result of per requisition efficiencies and continued execution of appropriate expense management during the period.

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

Research and Development Expenses	Six months ended June 30,	
	2021	2020
External expenses:		
PMA studies	\$ 31	\$ 111
Research and development employee-related expenses	4,936	4,373
Other internal research and development expenses	2,687	2,694
Total research and development expenses	<u>\$ 7,654</u>	<u>\$ 7,178</u>

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

Contingent consideration. Contingent consideration for the six months ended June 30, 2021 and 2020 was \$0 thousand and \$68 thousand of expense, respectively. Contingent consideration for the six months ended June 30, 2020 was attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Diagnostics, and potential amounts payable to former stockholders of OPKO Diagnostics in connection therewith pursuant to our acquisition agreement in October 2011.

Amortization of intangible assets. Amortization of intangible assets was \$15.1 million and \$19.8 million, respectively, for the six months ended June 30, 2021 and 2020. Amortization expense reflects the amortization of acquired intangible assets

with defined useful lives. Amortization expense declined during the three months ended June 30, 2021 due to acquired intangible assets becoming fully amortized.

Pharmaceuticals

(In thousands)	For the six months ended June 30,			
	2021	2020	Change	% Change
Revenues:				
Revenue from products	\$ 69,608	\$ 60,430	\$ 9,178	15 %
Revenue from transfer of intellectual property and other	13,816	24,239	(10,423)	(43)%
Total revenues	83,424	84,669	(1,245)	(1)%
Costs and expenses:				
Cost of revenue	49,201	35,292	13,909	39 %
Selling, general and administrative	27,525	26,670	855	3 %
Research and development	30,595	32,602	(2,007)	(6)%
Contingent Consideration	(1,059)	183	(1,242)	(679)%
Amortization of intangible assets	10,030	10,043	(13)	— %
Total costs and expenses	116,292	104,790	11,502	11 %
Loss from operations	(32,868)	(20,121)	(12,747)	63 %

Revenue. The increase in revenue from products for the six months ended June 30, 2021 compared to the six months ended June 30, 2020 was primarily attributable to an increase in sales at most of our international operating companies. Revenue from sales of *Royaldee* for the six months ended June 30, 2021 and 2020 was \$8.6 million and \$18.6 million, respectively. Sales of *Royaldee* have been negatively impacted as a result of challenges in onboarding new patients due to the COVID-19 pandemic. Revenue from transfer of intellectual property for the six months ended June 30, 2021 and 2020 principally reflected \$5.6 million and \$22.7 million, respectively, of revenue related to the Pfizer Transaction. Revenue from transfer of intellectual property for the three months ended June 30, 2021 also includes a \$5.0 million non-refundable upfront payment we will receive under the license agreement with Nicoya Therapeutics.

Cost of revenue. Cost of revenue for the six months ended June 30, 2021 increased \$13.9 million compared to the six months ended June 30, 2020. Cost of product revenue increased primarily due to an increase in inventory and material costs at most of our international operating companies, which was due to the increase in sales at our international operating companies and to a \$3.0 million inventory reserve recognized for *Royaldee* inventory for the six months ended June 30, 2021. This was partially offset by a decrease in sales of *Royaldee* for the six months ended June 30, 2021 compared to the six months ended June 30, 2020.

Selling, general and administrative expenses. Selling, general and administrative expenses for the six months ended June 30, 2021 and 2020 were \$27.5 million and \$26.7 million, respectively. The increase in selling, general and administrative expenses was primarily due to an increase in selling, general and administrative expenses for most of our international operating companies primarily due to higher variable costs from an increase in sales volume during the three months ended June 30, 2021. Selling, general and administrative expenses for the pharmaceutical segment for the six months ended June 30, 2021 and 2020 included equity-based compensation expense of \$0.7 million and \$0.5 million, respectively.

Research and development expenses. Research and development expenses for the six months ended June 30, 2021 and 2020 were \$30.6 million and \$32.6 million, respectively. Research and development expenses include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and premarket approval for diagnostics tests, if any. Internal expenses include employee-related expenses such as salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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

Research and Development Expenses	Six months ended June 30,	
	2021	2020
External expenses:		
Manufacturing expense for biological products	\$ 2,479	\$ 2,728
Phase III studies	5,011	5,339
Post-marketing studies	27	1,122
Earlier-stage programs	10,034	7,568
Research and development employee-related expenses	10,255	11,268
Other internal research and development expenses	2,813	4,577
Third-party grants and funding from collaboration agreements	(24)	—
Total research and development expenses	\$ 30,595	\$ 32,602

The decrease in research and development expenses for the six months ended June 30, 2021 was primarily due to a decrease in research and development expenses related to Somatrogen, a once-weekly human growth hormone injection for which we have partnered with Pfizer and successfully completed a phase 3 study in August 2019. Ongoing expenses on the Somatrogen program support open label extension studies that will continue until market launch of Somatrogen in certain countries, as well as the preparation of applications for marketing approvals. Research and development expenses for the pharmaceutical segment for the six months ended June 30, 2021 and 2020 included equity-based compensation expense of \$0.7 million and \$0.9 million, respectively.

Contingent consideration. Contingent consideration for the six months ended June 30, 2021 and 2020 was \$1.1 million reversal of expense and \$0.2 million of expense, respectively. Contingent consideration for the six months ended June 30, 2021 was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal and OPKO CURNA, and potential amounts payable to former stockholders of OPKO Renal and OPKO CURNA in connection therewith, pursuant to our acquisition agreements in March 2013 and January 2011, respectively. Contingent consideration for the six months ended June 30, 2020 was primarily attributable to changes in assumptions regarding the timing of achievement of future milestones for OPKO Renal, and potential amounts payable to former stockholders of OPKO Renal.

Amortization of intangible assets. Amortization of intangible assets was \$10.0 million and \$10.0 million, respectively, for the six months ended June 30, 2021 and 2020. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Our indefinite lived IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the FDA, the IPR&D assets will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Corporate

(In thousands)	For the six months ended June 30,		Change	% Change
	2021	2020		
Costs and expenses:				
Cost of revenue	\$ (20)	\$ (72)	\$ 52	(72)%
Selling, general and administrative	20,870	16,746	4,124	25 %
Research and development	(712)	(411)	(301)	73 %
Total costs and expenses	20,138	16,263	3,875	24 %
Loss from operations	(20,138)	(16,263)	(3,875)	24 %

Operating loss for our unallocated corporate operations for the six months ended June 30, 2021 and 2020 was \$20.1 million and \$16.3 million, respectively, and principally reflects general and administrative expenses incurred in connection with our corporate operations. The increase in operating loss for the six months ended June 30, 2021 was primarily attributable to an increase in legal and accounting fees incurred for the six months ended June 30, 2021, compared to the six months ended June 30, 2020.

Other

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

Interest expense. Interest expense for the six months ended June 30, 2021 and 2020 was \$10.3 million and \$11.0 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.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the six months ended June 30, 2021 and 2020, was \$0.7 million of expense and \$0.6 million reversal of expense, respectively. Derivative income (expense) for the six months ended June 30, 2021 and 2020, was principally related to the change in fair value on foreign currency forward exchange contracts at OPKO Chile.

Other income (expense), net. Other income (expense), net for the six months ended June 30, 2021 and 2020, was \$12.7 million of expense and \$5.9 million of income, respectively. Other expense for the six months ended June 30, 2021 primarily consisted of a \$11.1 million non-cash loss related to the exchange of \$55.4 million of the outstanding 2025 Notes for 19,051,270 shares of our Common Stock. Other income for the six months ended June 30, 2020 primarily consisted of net unrealized gain recognized during the period on our investment in VBI, offset by a net unrealized loss recognized during the period on our investment in Eloxx.

Income tax provision. Our income tax provision for the six months ended June 30, 2021 and 2020 was \$5.3 million and \$7.2 million, respectively, and reflects quarterly results using our expected effective tax rate. For the six months ended June 30, 2021, the tax rate differed from the U.S. federal statutory rate of 21% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Loss from investments in investees. We have made investments in certain early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report net losses. Loss from investments in investees was \$110 thousand and \$323 thousand for the six months ended June 30, 2021 and 2020, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2021, we had cash and cash equivalents of approximately \$65.8 million. Cash provided by operations of \$10.6 million for the six months ended June 30, 2021 principally reflects cash generated by our diagnostics segment due to the positive impact of COVID-19 testing volumes, which was partially offset by general and administrative expenses related to our corporate operations and research and development activities. Cash used in investing activities for the six months ended June 30, 2021 primarily reflects capital expenditures of \$18.2 million, which was partially offset by proceeds from the sale of equity securities of \$8.1 million. Cash used in financing activities of \$6.9 million primarily reflects net repayments on our lines of credit. We have historically not generated sustained positive cash flow sufficient to offset our operating and other expenses, and our primary sources of cash have been from the public and private placement of equity, the issuance of the 2033 Senior Notes, 2023 Convertible Notes and 2025 Notes and credit facilities available to us. However, as a result of the significant increase in testing volumes resulting from the COVID-19 pandemic, we have generated positive cash flow from operations; however we are unable to predict how long the demand will continue for our COVID-19 related testing, or whether pricing and reimbursement policies for testing will sustain, and accordingly, the sustainability of our cash flows from operations. We are unable to predict how long the demand will continue for our COVID-19 related testing, whether pricing and reimbursement policies for testing will sustain, or whether further restrictions will be placed on elective procedures or if stay at home orders will be reinstated and accordingly, the sustainability of the cash flow is uncertain.

In June 2021, we announced that EirGen Pharma Limited (“EirGen”), our wholly owned subsidiary, entered into a definitive agreement to sell one of its facilities in Waterford, Ireland to Horizon Therapeutics plc for \$65 million in cash less certain assumed and accrued liabilities relating to transferred employees. The facility houses EirGen’s sterile-fill-finish business and is no longer a core component of our ongoing operations and business strategy. The transaction closed in the third quarter of 2021.

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

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

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

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

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

As of June 30, 2021, the total commitments under our Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain were \$95.6 million, of which \$16.2 million was drawn as of June 30, 2021. At June 30, 2021, the weighted average interest rate on these lines of credit was approximately 5.4%. These lines of credit are short-term and are used primarily as a source of working capital. The highest aggregate principal balance at any time outstanding during the six months ended June 30, 2021 was \$17.2 million. We intend to continue to draw under these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

In November 2015, BioReference and certain of its subsidiaries entered into the Credit Agreement with CB, as lender. 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 composed of eligible accounts

receivables of BioReference and certain of its subsidiaries, as specified therein. As of June 30, 2021, \$64.3 million remained available for borrowing under the Credit Agreement.

In February 2018, in a transaction exempt from registration under the Securities Act, we issued the 2023 Convertible Notes in the aggregate principal amount of \$55.0 million maturing in February 2023. Each holder of a 2023 Convertible Note has the option, from time to time, to convert all or any portion of the outstanding principal balance of such 2023 Convertible Note, together with accrued and unpaid interest thereon, into shares of our Common Stock, par value \$0.01 per share, at a conversion price of \$5.00 per share of Common Stock. We may redeem all or any part of the then issued and outstanding 2023 Convertible Notes, together with accrued and unpaid interest thereon upon no fewer than 30 days, and no more than 60 days, notice to the holders. The 2023 Convertible Notes contain customary events of default and representations and warranties of OPKO.

On July 6, 2021, we entered into the CAMP4 Agreement with CAMP4, pursuant to which we granted to CAMP4 an exclusive license to develop, manufacture, commercialize or improve therapeutics utilizing the AntagoNAT technology, an oligonucleotide platform developed under OPKO CURNA, which includes the Licensed Compound and the Licensed Product, worldwide. The License grant covers human pharmaceutical, prophylactic, and therapeutic and certain diagnostic uses.

We received an initial upfront payment of \$1.5 million and 3,373,008 shares of CAMP4's Preferred Stock, which equates to approximately 5% of the outstanding shares of CAMP4, and are eligible to receive up to \$3.5 million in development milestone payments for Dravet syndrome products, and \$4 million for non-Dravet syndrome products, as well as sales milestones of up to \$90 million for Dravet syndrome products and up to \$90 million for non-Dravet syndrome products. We may also receive double digit royalty payments on the net sales of royalty bearing products, subject to adjustment. In addition, upon achievement of certain development milestones, we will be eligible to receive additional equity consideration of up to 5,782,299 shares of Preferred Stock in connection with Dravet syndrome products and up to 1,082,248 shares of Preferred stock in connection with non-Dravet syndrome products.

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

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

EirGen received an initial upfront payment of \$5 million and is eligible to receive an additional \$5 million upon the first to occur of (A) a certain predetermined milestone, or (B) the first anniversary of the effective date. EirGen is also eligible to receive up to an additional aggregate amount of \$115 million upon the achievement of certain development, regulatory and sales-based milestones by Nicoya for the Nicoya Product in the Nicoya Territory. EirGen will also receive tiered, double digit royalty payments at rates in the low double digits on net product sales within the Nicoya Territory and in the Nicoya Field.

On October 12, 2017, EirGen and JT entered into the JT Agreement granting JT the exclusive rights for the development and commercialization of *Royaldee* in Japan. On May 17, 2021, JT delivered to the Company a notice of termination of the Development Agreement pursuant to Section 16.1(a) thereof, which permits termination by JT for any reason, indicating its decision to discontinue development of *Royaldee* for the Japanese market based on a comprehensive review of its development pipeline.

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

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

As part of the arrangement, the companies will share responsibility for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. For the initial development plan, the companies have agreed to certain cost sharing arrangements. VMCRP will be responsible for all other development costs that VMCRP considers necessary to develop the product for the VMCRP Initial Indication in the VMCRP Territory except as otherwise provided in the VMCRP Agreement. EirGen also granted to VMCRP 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, VMCRP 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. VMCRP 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.

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

In 2014, Pfizer and OPKO entered into a worldwide agreement for the development and commercialization of our long-acting Somatrogen for the treatment of GHD in adults and children, as well as for the treatment of growth failure in children born small for gestational age. In May 2020, we entered into a Restated Agreement with Pfizer which was effective as of January 1, 2020, pursuant to which the parties agreed to share all costs for Manufacturing Activities, as defined in the Restated Agreement, for developing a licensed product for the three indications included in the Restated Agreement. Under the terms of the agreements with Pfizer, we received non-refundable and non-creditable upfront payments of \$295 million in 2015 and are eligible to receive up to an additional \$275 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize Somatrogen worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of Somatrogen for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of Somatrogen for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both Somatrogen and Pfizer's Genotropin®. During the first quarter of 2021, regulatory submissions in the major global markets for Somatrogen have been accepted including, the U.S., European Medicines Agency, and Ministry of Health, Labour, and Welfare in Japan for Somatrogen for the treatment of pediatric patients with GHD.

In connection with our acquisitions of CURNA, OPKO Diagnostics and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events, including up to an additional \$19.1 million in shares of our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones; and up to an additional \$125.0 million in either shares of our Common Stock or cash, at our option subject to the achievement of certain milestones, to the former shareholders of OPKO Renal.

We believe that the cash and cash equivalents on hand at June 30, 2021, cash from operations, the cash received from the sale of one of our facilities in Waterford, Ireland to Horizon Therapeutics plc and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements, and the timing of those requirements, will depend on a number of factors, including the impact of the COVID-19 pandemic on our business, the approval and success of our products in development, particularly our long acting Somatrogen for which we have submitted for approval in the U.S., Europe and Japan, the commercial success of *Royaldee*, including the launch of *Royaldee* by Vifor expected in 2022, BioReference's financial performance, possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, our success in developing markets for our product candidates and results of government investigations, payor claims, and legal proceedings that may arise, including, without limitation class action and derivative litigation to which we are subject, and our ability to obtain insurance

coverage for such claims. We have historically not generated sustained positive cash flow and if we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions or reduce our marketing or sales efforts or cease operations.

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

The following table provides information as of June 30, 2021, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining six months ending December 31, 2021	2022	2023	2024	2025	Thereafter	Total
Open purchase orders	\$ 134,832	\$ 660	\$ —	\$ —	\$ —	\$ —	\$ 135,492
Operating leases	4,501	10,457	7,076	4,926	3,013	10,734	40,707
Finance leases	1,183	1,573	997	680	210	—	4,643
2033 Senior Notes, 2025 and 2023 Convertible Notes	—	—	58,050	—	116,009	—	174,059
Mortgages and other debts payable	599	1,016	815	723	241	193	3,587
Lines of credit	16,197	—	—	—	—	—	16,197
Interest commitments	3,516	6,638	20,048	6,535	573	—	37,310
Total	\$ 167,825	\$ 22,297	\$ 86,986	\$ 12,864	\$ 120,047	\$ 10,927	\$ 420,946

The preceding table does not include information where the amounts of the obligations are not currently determinable, including the following:

- Contractual obligations in connection with clinical trials, which span over two years, and that depend on patient enrollment. The total amount of expenditures is dependent on the actual number of patients enrolled and as such, the contracts do not specify the maximum amount we may owe.
- Product license agreements effective during the lesser of 15 years or patent expiration whereby payments and amounts are determined by applying a royalty rate on uncapped future sales.
- Contingent consideration that includes payments upon achievement of certain milestones including meeting development milestones such as the completion of successful clinical trials, NDA approvals by the FDA and revenue milestones upon the achievement of certain revenue targets all of which are anticipated to be paid within the next seven years and are payable in either shares of our Common Stock or cash, at our option, and that may aggregate up to \$144.1 million.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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

RECENT ACCOUNTING PRONOUNCEMENTS

Pending accounting pronouncements.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

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

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

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

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

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

At June 30, 2021, we had cash and cash equivalents of \$65.8 million. The weighted average interest rate related to our cash and cash equivalents for the six months ended June 30, 2021 was less than 1%. As of June 30, 2021, the principal outstanding balances under BioReference's Credit Agreement with CB and our Chilean and Spanish lines of credit was \$16.2 million in the aggregate at a weighted average interest rate of approximately 5.4%.

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

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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

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

Changes to the Company's Internal Control Over Financial Reporting

There have been no changes to the Company's internal control over financial reporting that occurred during the quarter ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are, from time to time, party to various legal proceedings arising out of our business. During the reporting period, covered by this Quarterly Report on Form 10-Q, except as set forth below, there have been no material changes to the description of legal proceedings set forth in our Annual Report on Form 10-K for the year ended December 31, 2020. The following should be read in conjunction with the information provided in Part I, Item 3 of such Annual Report.

As previously reported, on or about September 13, 2018, Idan Sharon filed an Application for Approval of a Class Action in the Tel Aviv Israel District Court against the Company and certain of its current and former executive officers, and certain members of its Board of Directors (the “Sharon Claim”). This application was filed by a purported stockholder, both individually and on behalf of a putative class of the Company’s stockholders, claiming that in connection with the facts and circumstances underlying the allegations in the SEC Complaint filed in 2018 and which case was settled, the Company engaged in fraudulent conduct and made false and misleading statements of material fact or omitted to state material facts necessary to make the statements made not misleading. The Sharon Claim sought both to declare the action a class action and monetary damages. The Tel Aviv District Court closed this case pending resolution of the U.S.-based class actions relating to the allegations in the SEC Complaint. The U.S. class action lawsuit has now been settled, and the damages granted in the settlement are for both NASDAQ and the Tel Aviv Stock Exchange (“TASE”) class members (the “Settlement Agreement”). In July 2021, Sharon notified the Company that he intends to file a motion and request the Court to order the members of the TASE to provide the information required to allow distribution of payment to TASE class members, in accordance with the Settlement Agreement.

As previously reported, on or about September 16, 2018, Dalia Avraham filed an Application for Approval of a Class Action in the Tel Aviv Israel District Court against the Company and Dr. Frost. This application was filed by a purported stockholder, both individually and on behalf of a putative class of the Company’s stockholders (the “Avraham Claim”). The Avraham Claim alleged a negligent and/or deliberate act related to the trade of the Company’s shares on the TASE which was intended to or which in fact caused damage to the Company’s investors based on the Company’s decision to delist from TASE in April 2018 and its subsequent decision to continue to be listed on TASE. The Avraham Claim sought to declare the action to be a class action and an estimated NIS 20 million (approximately USD \$6.1 million) in damages. On June 24, 2021, the Tel Aviv District Court granted the parties’ joint motion to withdraw and dismissed the case, subject to the payment of NIS 45,000 (approximately USD \$14,000.00) to the plaintiff’s counsel and NIS 4,000 (approximately USD \$1,200.00) to a plaintiff in the case within 60 days from the Court’s judgment.

As previously reported, on April 8, 2019, MabVax Therapeutics Holdings, Inc. filed a lawsuit in the Superior Court of California, County of San Diego against a number of individuals and entities, including the Company, Dr. Frost, Steven Rubin, the Company’s Executive Vice President-Administration, and an entity affiliated with Dr. Frost, based on the allegations raised in the SEC Complaint. The lawsuit seeks an award for actual and punitive damages, pre- and post-judgment interest; that the defendants be required to make full disclosure and accounting of their interests and transactions in plaintiff’s securities; costs of the suit, and reasonable attorney’s fees; and such other legal and equitable relief as the Court may deem proper under the circumstances. The complaint was subsequently amended. The Company filed a demurrer to the first amended complaint on November 2, 2020. An order on the demurrer was entered on May 27, 2021, pursuant to which the third cause of action for Unlawful Business Practices in violation of Business & Professions Code section 17200 was dismissed and demurrer on the sixth and seventh causes of action for Constructive Fraud and Negligent Misrepresentation was sustained, but the Court gave MabVax leave to amend the complaint, which it did, but did not include the sixth and seventh causes of action. The Company believes the allegations against the Company, Dr. Frost and Mr. Rubin are without merit and continue to vigorously defend against the claims.

As previously mentioned, BioReference receives and is routinely required to respond to CIDs in the ordinary course of business. On November 26, 2019, BioReference received a CID from the U.S. Department of Justice (“DOJ”). The CID states that DOJ is investigating whether BioReference paid unlawful remuneration to health care practitioners in violation of the Anti-Kickback Statute or Stark law and thus submitted or caused to be submitted false claims to government health care programs in violation of the False Claims Act. The time period covered by DOJ’s requests is January 1, 2011 through November 26, 2019. BioReference has fully cooperated with the DOJ by submitting the requested information and making current employees available for interviews, and DOJ recently made a presentation to BioReference regarding its position. BioReference is reviewing the allegations made by DOJ. While BioReference intends to vigorously defend itself with respect to the claims, the parties have begun to discuss settlement.

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

Item 1A. Risk Factors

Except as set forth in this Item 1A, there have been no material changes to our risk factors as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit 10.1	Form of Exchange Agreement, dated as of May 6, 2021, by and between OPKO Health Inc. and the applicable Noteholder (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed on May 7, 2021).
Exhibit 10.2	Asset Purchase Agreement, dated June 16, 2021, among EirGen Pharma Limited, Horizon Therapeutics Ireland DAC, and OPKO Health, Inc. (with respect to certain sections).
Exhibit 10.3*	License Agreement by and among EirGen Pharma Limited and Nicoya Macua Limited, dated June 18, 2021.
Exhibit 10.4*	Exclusive License Agreement by and between OPKO Health, Inc. and CAMP4 Therapeutics Corporation, dated July 6, 2021.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2021.
Exhibit 31.2	Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2021.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2021.
Exhibit 32.2	Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended June 30, 2021.
Exhibit 101.INS	Inline XBRL Instance Document
Exhibit 101.SCH	Inline XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	inline XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
Exhibit 104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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

SIGNATURES

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

Date: July 29, 2021

OPKO Health, Inc.

/s/ Adam Logal

Adam Logal
Senior Vice President and Chief Financial
Officer

ASSET PURCHASE AGREEMENT

Among

EirGen Pharma Limited,

Horizon Therapeutics Ireland DAC

And

OPKO Health, Inc. (solely for the purposes of Sections 2.1, 8.3 and 11.16)

Dated as of June 16, 2021

TABLE OF CONTENTS

	<u>Page</u>
ARTICLE I DEFINITIONS AND RULES OF CONSTRUCTION	1
1.1 Definitions	1
1.2 Rules of Construction.	9
ARTICLE II PURCHASE AND SALE; ASSUMPTION OF LIABILITIES	10
2.1 Purchase and Sale of the Transferred Assets.	10
2.2 Transferred Liabilities; Retention by Seller of Excluded Liabilities.	10
2.3 Consent to Assignment.	11
ARTICLE III PURCHASE PRICE AND ADJUSTMENTS	12
3.1 Purchase Price.	12
3.2 Allocation of Purchase Price.	12
3.3 Withholding.	12
ARTICLE IV REPRESENTATIONS AND WARRANTIES OF SELLER	12
4.1 Corporate Existence and Solvency.	13
4.2 Corporate Authority.	13
4.3 No Conflicts; Governmental Approvals and Consents.	13
4.4 Sufficiency of Assets.	14
4.5 Title to Transferred Assets.	14
4.6 Real Estate.	15
4.7 Transferred Contracts.	17
4.8 Litigation.	17
4.9 Compliance with Laws; Permits; Regulatory Compliance.	17
4.10 Anti-Corruption; International Trade.	18
4.11 Intellectual Property.	19
4.12 Privacy and Data Security.	21
4.13 Product Liability.	22
4.14 Tax Matters.	22
4.15 Benefit Plans.	22
4.16 Labor Matters.	23
4.17 Environmental Matters.	24

**TABLE OF CONTENTS
CONTINUED**

Page

4.18	Affiliate Agreements	25
4.19	Powers of Attorney	25
4.20	Business Records	26
4.21	Brokers and Other Advisors.	26
ARTICLE V REPRESENTATIONS AND WARRANTIES OF PURCHASER		26
5.1	Corporate Existence.	26
5.2	Corporate Authority.	26
5.3	Governmental Approvals and Consents.	27
5.4	Litigation.	27
5.5	Financial Capacity.	27
5.6	Brokers and Other Advisors.	27
ARTICLE VI AGREEMENTS OF PURCHASER AND SELLER		27
6.1	Conduct of the Business.	27
6.2	Investigation of Business.	29
6.3	Necessary Efforts; No Inconsistent Action.	29
6.4	Public Disclosures; Confidentiality.	30
6.5	Access to Records.	31
6.6	TUPE and Employee Benefits.	32
6.7	Non-Solicitation; No-Hire.	36
6.8	Tax Matters.	37
6.9	Mail Handling.	38
6.10	Wrong Pockets.	38
6.11	Release of Liens; Accounts Payable.	39
6.12	Shared Contracts.	39
6.13	Business Materials; Transferred Personal Property.	40
6.14	Post-Closing Responsibilities.	40
ARTICLE VII CONDITIONS TO CLOSING		41
7.1	Conditions Precedent to Obligations of Purchaser and Seller.	41
7.2	Conditions Precedent to Obligation of Purchaser.	41
7.3	Conditions Precedent to Obligation of Seller.	42
ARTICLE VIII CLOSING		43
8.1	Closing Date.	43

**TABLE OF CONTENTS
CONTINUED**

Page

8.2	Purchaser Obligations.	43
8.3	Seller Obligations.	44
ARTICLE IX	INDEMNIFICATION	45
9.1	Survival.	45
9.2	Indemnification by Seller.	45
9.3	Indemnification by Purchaser.	46
9.4	Limitations on Indemnification.	46
9.5	Indemnification Procedures.	48
9.6	Mitigation.	51
9.7	Treatment of Indemnification Payments.	51
ARTICLE X	TERMINATION	51
10.1	Termination Events.	51
10.2	E(ffect of Termination.	52
ARTICLE XI	MISCELLANEOUS	53
11.1	Notices.	53
11.2	Bulk Transfers.	54
11.3	Severability.	54
11.4	Further Assurances; Further Cooperation.	55
11.5	Counterparts.	55
11.6	Expenses.	55
11.7	Assignment; Successors and Assigns.	55
11.8	Amendment; Waiver.	56
11.9	Remedies.	56
11.10	Third Parties.	57
11.11	Governing Law.	57
11.12	Dispute Resolution.	57
11.13	Disclosure Schedules.	58
11.14	Entire Agreement.	59
11.15	No Joint Venture.	59
11.16	Parent Guarantee.	59
11.17	Section Headings; Table of Contents.	60

EXHIBITS

- Exhibit A – Excluded Assets
- Exhibit B – Excluded Liabilities
- Exhibit C – Transferred Assets
- Exhibit D – Transferred Liabilities
- Exhibit E – Form of Assignment and Assumption Agreement
- Exhibit F – Form of Transition Services Agreement
- Exhibit G – Form of Transfer
- Exhibit H – Excluded Business Assets
- Exhibit I – Form of Collateral Warranty Assignment Deed
- Exhibit J – Form of Contract for Sale

ASSET PURCHASE AGREEMENT

This **Asset Purchase Agreement** is dated as of June 16, 2021, among **OPKO Health, Inc.**, a Delaware corporation (“Parent”) (solely for the purposes Sections 2.1, 8.3 and 11.16) and **EirGen Pharma Limited**, a private limited company incorporated under the laws of Ireland registered with the Irish Companies Office under company number 398605 (“Seller”), and **Horizon Therapeutics Ireland DAC**, a designated activity company incorporated under the laws of Ireland registered with the Irish Companies Office under company number 376554 (“Purchaser”) (each, a “Party” and collectively, the “Parties”). Capitalized terms used in this Agreement shall have the meanings indicated in Section 1.1.

RECITALS

A. Seller, among other things, is engaged in the business of owning and operating a manufacturing and R&D facility used for sterile fill finish of biologics pharmaceutical products;

B. Seller owns certain Assets used in the operation of the Facility;

C. contemporaneously with the execution of this Agreement, Purchaser and Seller entered into that certain Transition Services Agreement in the form of Exhibit F (the “Transition Services Agreement”); and

D. Purchaser desires to purchase and assume, and Seller desires to sell, transfer, convey, assign and deliver the Transferred Assets and the Transferred Liabilities to Purchaser, upon the terms and subject to the conditions specified in this Agreement.

NOW, THEREFORE, in consideration of the mutual representations, warranties, covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I DEFINITIONS AND RULES OF CONSTRUCTION

1.1 Definitions. Unless otherwise provided herein, capitalized terms used in this Agreement shall have the following meanings:

“Accrued PTO Amount” shall have the meaning set forth in Section 6.6(k).

“Affiliate” of a Person means a Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, the first mentioned Person. For purposes of this definition, “control,” when used with respect to any specified Person, means the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through ownership of voting securities or by contract or otherwise, and the terms “controlling” and “controlled by” have meanings correlative to the foregoing.

“Affiliate Agreement” shall mean all Contracts (x) between members of the Seller Group or (y) between a member of the Seller Group, on the one hand, and any directors or officers of any member of the Seller Group, on the other hand, excluding employment agreements and indemnity agreements.

“Agreement” shall mean this Asset Purchase Agreement, as amended from time to time in accordance with its terms.

“AIB” shall mean Allied Irish Banks plc., a public limited company incorporated in Ireland, with company registration number 24173, having its registered address at 10 Molesworth Street, Dublin 2, Ireland.

“AIB Charges” shall mean the security granted in favor of Allied Irish Banks plc pursuant to (a) the charge, dated 29 May 2018, between (i) Seller and (ii) AIB and (b) the related PRA Form 52, dated 29 May 2018, between (i) Seller and (ii) AIB.

“AIB Loan” shall mean the loan advanced by AIB pursuant to the letter of sanction, dated 2 May 2018, between (a) Seller and (b) AIB.

“Anti-Corruption Laws” shall mean all applicable U.S. and non-U.S. Laws relating to the prevention of corruption and bribery, including the FCPA and the UK Bribery Act of 2010 and the Irish Criminal Justice (Corruption Offences) Act 2018 (as amended).

“Assets” shall mean, with respect to any Person, all assets, properties, rights and claims of every nature, kind and description, tangible and intangible, owned or leased or licensed, wheresoever located and whether or not carried or reflected on the books or records of such Person.

“Assignment and Assumption Agreement” shall have the meaning set forth in Section 8.2(a).

“Assumed Employee-Related Liabilities” shall have the meaning set forth in Section 6.6(j)(ii).

“Benefit Plan” shall mean each “employee benefit plan” and each other employment, change in control, retention, bonus, commission, defined benefit or defined contribution, pension, profit sharing, deferred compensation, stock ownership, stock purchase, stock option, stock appreciation, restricted stock, restricted stock unit, phantom stock or other equity-based compensation, retirement, vacation, severance, redundancy, termination, disability, death benefit, medical, dental, or other employee compensation and benefit plan, policy, program, agreement or arrangement, in each case, that Seller or its Subsidiaries sponsor, maintain or contribute to (or are required to contribute to) with respect to any Business Employees or have any Liability with respect to, for the benefit of Business Employees and their beneficiaries and dependents.

“Books and Records” shall have the meaning set forth in Section 6.5(c).

“Business” shall mean the business of drug product manufacturing, and related laboratory operations, as currently conducted or proposed to be conducted by Seller in respect of sterile drug products at the Facility, except that Business does not include any Excluded Business, Excluded Contracts or any Contracts with any third parties or any Seller Group members to manufacture any sterile drug products or Contracts with any third parties to provide research and development services.

“Business Acquisition Proposal” means an indication of interest, offer or proposal to acquire, directly or indirectly, (i) the Business or (ii) all or any substantial portion of the Transferred Assets, in each case, in a single transaction or series of related transactions (whether such acquisition is structured as a sale of stock, sale of assets, merger, recapitalization or otherwise, other than the transactions contemplated by this Agreement).

“Business Day” shall mean any day other than a Saturday, a Sunday or a day on which banks in New York City, United States of America or Dublin, Ireland are permitted or required by Law to be closed.

“Business Employee” shall mean (i) each employee of Seller who is engaged wholly or predominantly in the provision of services to the Business, (ii) each other employee of Seller or any of its Subsidiaries whose transfer to Purchaser and its Affiliates is required in connection with the transactions contemplated hereby under applicable local Laws, (iii) any employee who would be entitled to transfer to Purchaser in connection with the transactions contemplated hereby under applicable local Laws but who refuses to do so and (iv) each other employee of Seller or any of its Subsidiaries who Seller and Purchaser have, prior to the Closing Date, mutually agreed will transfer to Purchaser and its Affiliates; in the case of each of clauses (i), (ii) and (iii), each of whom is listed in Section 1.1(a) of the Disclosure Schedules.

“Business Employee List” shall have the meaning set forth in Section 6.6(a).

“Business Portion” shall have the meaning set forth in Section 6.12.

“Business Software” shall have the meaning set forth in Section 4.11(g).

“CGT Clearance Certificate” shall mean a tax clearance certificate issued pursuant to Section 980 of the Taxes Consolidation Act 1997 (as amended).

“Closing” shall have the meaning set forth in Section 8.1.

“Closing Date” shall have the meaning set forth in Section 8.1.

“Collateral Warranty Assignment Deed” shall mean the deed of assignment in respect of certain collateral warranties related to the Facility, substantially in the form attached hereto as Exhibit I and subject to finalization of the scope of collateral warranties to be assigned.

“Companies Act” shall mean the Irish Companies Act 2014 and every other enactment which is to be read together with the Companies Act.

“Consent” shall have the meaning set forth in Section 6.3.

“Contract” shall mean any agreement, contract, subcontract, license, sublicense, lease, indenture, purchaser order or other legally binding commitment or undertaking of any nature.

“Contract for Sale” means the contract for the sale of the Property by the Seller to the Purchaser, to include the Law Society of Ireland General Conditions for Sale 2019 substantially in the form attached hereto as Exhibit J.

“Data Room” shall mean the “Orbit” virtual data room operated by Parent.

“Data Subject” shall have the meaning set forth in the GDPR.

“Deductible” shall have the meaning set forth in Section 9.4(b).

“Deferred Asset” shall have the meaning set forth in Section 2.3(a).

“Direct Claim” shall have the meaning set forth in Section 9.5(b).

“Disclosure Schedules” shall have the meaning set forth in the first sentence of Article IV.

“Dollars” or “\$”, when used in this Agreement or any other Transaction Document, shall mean United States dollars unless otherwise stated.

“Effect” shall mean any change, effect, event, occurrence, state of facts or development.

“Effective Time” shall have the meaning set forth in Section 8.1.

“Employee Representative” shall have the meaning set forth in Section 4.16(a).

“Environmental Claim” shall mean any written claim, proceeding, suit, complaint, or notice of violation alleging violation of, or liability under, any Environmental Laws.

“Environmental Laws” shall mean any applicable Laws, Permits, decrees, orders or common law relating to, or imposing standards regarding the protection of the environment.

“Excluded Assets” shall mean the Assets set forth in Exhibit A.

“Excluded Business” shall mean (i) sales operations of all kinds and any commercial manufacturing business conducted by the Seller with or for members of the Seller Group and/or its customers, and (ii) the research and development activities relating to oral solid dose product manufacturing and related laboratory operations relating to oral solid dose product manufacturing, conducted by Seller at the Facility through the use of the Excluded Business Assets.

“Excluded Business Assets” shall mean all plant, machinery, equipment and other tangible personal property located at the Facility that is specifically listed in Exhibit H hereto.

“Excluded Contracts” shall have the meaning set forth in Exhibit A.

“Excluded Employee-Related Liabilities” shall have the meaning set forth in Section 6.6(j).

“Excluded Liabilities” shall mean the Liabilities set forth in Exhibit B.

“Facility” shall have the meaning set forth in Exhibit C.

“FCPA” means the U.S. Foreign Corrupt Practices Act of 1977, as amended.

“Fraud” shall mean intentional misrepresentation with respect to the representations and warranties set forth in this Agreement or in any other Transaction Document that constitutes common law fraud under Irish law.

“GDPR” shall mean (as the context permits) the EU General Data Protection Regulation (EU 2016/679) or the General Data Protection Regulation as adopted in the UK pursuant to the European Union (Withdrawal Act) 2018.

“Good and Marketable Title” means a title commensurate with prudent standards of correct and current conveyancing practice in Ireland.

“Governmental Authority” shall have the meaning set forth in Section 4.3(a).

“Hazardous Materials” shall mean any natural or artificial substance or combination of substances (whether in solid, liquid, gas, vapor or other form whatsoever) capable of causing harm to the environment or human health including any hazardous, toxic or dangerous substance or article or element, petroleum, petroleum products and asbestos.

“Held Asset” shall have the meaning set forth in Section 6.10(a).

“holding company” has the meaning given to it in section 8 of the Companies Act;

“Indemnification Claim Notice” shall have the meaning set forth in Section 9.5(a).

“Indemnified Party” shall have the meaning set forth in Section 9.4.

“Indemnifying Party” shall have the meaning set forth in Section 9.4.

“Intellectual Property” shall mean all rights associated with the following: (a) patents and applications therefor, utility models and applications therefor and statutory invention registrations (including any continuations, continuations-in-part, divisionals, reissues, renewals, foreign counterparts or modifications for any of the foregoing); (b) trade secret rights, rights in know-how and all other rights in or to confidential business or technical information (“Trade Secrets”); (c) copyrights in works of authorship of any type (including copyrights in software), mask work rights and design rights, whether or not registered, and registrations and applications for registration thereof, and all rights therein provided by applicable international treaties or conventions, all moral and common law rights thereto; (d) trademarks, trade names, service marks, service names, trade dress rights, domain names, social media identifiers, URLs, IP addresses, IP address ranges and websites and similar designation of origin, in each case whether registered or unregistered, and all goodwill symbolized thereby and associated therewith; and (e) any similar, corresponding or equivalent rights to any of the foregoing anywhere in the world.

“Interim Period” shall have the meaning set forth in Section 6.1(a).

“IHPRA” shall have the meaning set forth in Section 4.9(c).

“Initial Press Releases” has the meaning set forth in Section 6.4.

“Labor Contract” shall have the meaning set forth in Section 4.16(a).

“Law” shall mean any law, treaty, statute, EU Directive, EU Regulation, enactment, ordinance, rule, decree, code, statutory instrument or regulation of a Governmental Authority.

“Liabilities” shall mean any liabilities, obligations, guarantees (including lease guarantees), commitments, damages, losses, debts, judgments or settlements of any nature or kind, whether known or unknown, fixed, accrued, absolute or contingent, liquidated or unliquidated, matured or unmatured.

“Liens” shall mean any mortgage, easement, lease, sublease, right of way, trust or title retention agreement, pledge, lien (including any lien for unpaid Taxes), charge, security interest, adverse claim, option, assignment, hypothecation, title retention or any restriction or other encumbrance or security agreement of any kind.

“Losses” shall mean any and all losses, damages (including consequential damages), liabilities, costs (including reasonable out-of-pocket costs of investigation) and expenses, including interest,

penalties, settlement costs, judgments, awards, fines, costs of mitigation or remediation, court costs and fees (including reasonable attorneys' fees and expenses).

“Non-Business Portion” shall have the meaning set forth in Section 6.12.

“Omitted Asset” shall have the meaning set forth in Section 6.10(b).

“Order” shall mean any judgment, decree, order, writ, award, assessment, ruling or injunction of a court or other Governmental Authority of competent jurisdiction.

“ordinary course of business” shall mean in the ordinary course of the operation of the Business.

“Outside Date” shall have the meaning set forth in Section 10.1(b).

“Party” and “Parties” shall have the respective meanings set forth in the Recitals to this Agreement.

“Permits” shall have the meaning set forth in Exhibit C.

“Permitted Liens” shall mean mechanics', workmen's, repairmen's, warehousemen's, carriers' or other similar Liens, including all statutory Liens, or notices of commencement or similar filings, arising or incurred in the ordinary course of business with respect to any amounts not yet due and payable or which are being contested in good faith through (if then appropriate) appropriate proceedings.

“Person” shall mean an individual, corporation, partnership, limited liability company, association, trust, incorporated organization, other entity or group.

“Personal Data” shall have the meaning set forth in the GDPR.

“Proceeding” shall mean any claim, action, arbitration, audit, hearing, inquiry, examination proceeding, litigation or suit (whether civil, criminal or administrative) commenced, brought, conducted, or heard by or before, or otherwise involving any Governmental Authority or arbitrator.

“Processed/Processing” shall have the meaning set forth in the GDPR.

“Property” shall mean all that and those the properties comprised in Folio 6899L County Waterford held under lease dated 3 March 2017 between Industrial Development Agency (Ireland) and Seller for a term of 999 years and Folio 6900L County Waterford held under lease dated 3 March 2017 between Industrial Development Agency (Ireland) and Seller for a term of 999 years.

“Publicly Available Software” shall mean each of: (i) any software that contains, or is derived in any manner (in whole or in part) from, any software that is distributed as free software, “copyleft,” open source software (e.g. Linux), or similar licensing and distribution models; and (ii) any software that requires as a condition of use, modification, or distribution of such software that such software or other software or technology incorporated into, derived from, or distributed with such software: (a) be disclosed or distributed in source code form; (b) be licensed for the purpose of making derivative works; or (c) be redistributable at no or minimal charge (such licenses under this clause (ii) being “Hereditary Licenses”). Publicly Available Software includes software licensed or distributed under any of the following licenses or distribution models similar to any of the following: (a) GNU General Public License (GPL) or Lesser/Library GPL (LGPL), (b) the Artistic License (e.g. PERL), (c) the Mozilla Public License, (d) the

Netscape Public License, (e) the Sun Community Source License (SCSL), the Sun Industry Source License (SISL), and the Apache Server License.

“Purchase” shall mean the purchase and sale of the Transferred Assets and the assumption of the Transferred Liabilities on the terms set forth in this Agreement and the other Transaction Documents.

“Purchase Price” shall have the meaning set forth in Section 3.1.

“Purchase Price Allocation” shall have the meaning set forth in Section 3.2.

“Purchaser” shall have the meaning set forth in the Recitals to the Agreement.

“Purchaser Fundamental Representations” means the representations and warranties of Purchaser set forth in Sections 5.1, 5.2(a) and 5.6.

“Purchaser Group” shall mean the Purchaser and any other company which is or becomes, directly or indirectly, a subsidiary or holding company of the Purchaser or a subsidiary of such holding company.

“Purchaser Indemnified Persons” shall have the meaning set forth in Section 9.2.

“Purchaser Material Adverse Effect” shall mean a material adverse effect on the ability of Purchaser and/or its Affiliates, as applicable, to perform their respective obligations under this Agreement in a timely manner or to consummate the transactions contemplated by this Agreement.

“Redemption Payment” shall have the meaning set forth in Section 8.2.

“Representative” shall mean, with respect to any Person, any officer, director, principal, partner, manager, member, attorney, accountant, agent, employee, consultant, financial advisor or other authorized representative of such Person.

“Restricted Employee(s)” shall have the meaning set forth in Section 6.7(b).

“Retained Business” means any and all of the businesses conducted by members of the Seller Group (other than the Business).

“Retained Employee” shall mean each individual employed or engaged by the Seller or any of its Affiliates as of the date of this Agreement, or between the date of this Agreement and the Closing Date (including any such employee who is on sick leave, military leave, vacation, holiday, disability or other similar leave of absence), who is not a Transferred Employee.

“Sanctioned Country” shall mean a country or territory which is itself the subject of or target of comprehensive Sanctions (at the time of this Agreement Crimea, Cuba, Iran, North Korea, Syria, Venezuela and Turkey).

“Sanctioned Person” shall mean a Person (i) listed on any Sanctions-related list of designated Persons maintained by a Governmental Authority, (ii) located, organized, or resident in a Sanctioned Country, or (iii) greater than 50% owned or controlled by one or more Persons described in clauses (i) or (ii) above.

“Sanctions” shall mean any Laws in any part of the world related to import transactions, export transactions, or economic or trade sanctions or restrictions; the economic sanctions rules and regulations implemented under statutory authority or the U.S. President’s Executive Orders and administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury or U.S. Department of State; European Union Council Regulations on sanctions; United Nations sanctions policies and Laws; economic sanctions administered by Her Majesty’s Treasury of the United Kingdom, the European Union or other relevant sanctions authority; and all relevant Laws made under any of the foregoing.

“Seller” shall have the meaning set forth in the Recitals to this Agreement.

“Seller Fundamental Representations” means the representations and warranties of Seller set forth in Sections 4.1, 4.2, 4.5(a), 4.11(a), 4.18, 4.21 and 11.16(b).

“Seller Group” shall mean the Seller, Parent and any other company which is or becomes, directly or indirectly, a subsidiary or holding company of the Seller or a subsidiary of such holding company.

“Seller Group Indemnified Persons” shall have the meaning set forth in Section 9.3.

“Seller Pension Scheme” shall mean Eirgen Pharma Defined Contribution Pension Plan operated by the Seller.

“Severance Obligations” shall mean any statutory, contractual, common law or other severance or redundancy payments or other separation benefits, whether pursuant to applicable Law, any applicable plan or policy, any applicable individual employment agreement or arrangement, or otherwise and the employer portion of any Taxes payable in connection therewith. For the avoidance of doubt, Severance Obligations shall not include any severance compensation or benefits not required to be paid by applicable Law, or an applicable Benefit Plan or corresponding plan, policy, program, agreement or arrangement of Purchaser and its Affiliates.

“Subsidiary” or “Subsidiaries” shall have the meaning given to it in section 7 of the Companies Act.

“Tax” or “Taxes” shall mean any federal, state, local or non-U.S. tax of any kind whatsoever, including income, alternative, minimum, accumulated earnings, personal holding company, franchise, unincorporated business, capital stock, net worth, capital, profits, windfall profits, gross receipts, value added, sales, use, excise, custom duties, transfer, conveyance, mortgage, registration, stamp, documentary, recording, premium, severance, environmental, real and personal property, ad valorem, intangibles, rent, occupancy, license, occupational, employment, unemployment insurance, social security (including both employee and employer social security contributions), disability, workers’ compensation, payroll, health care, escheat, withholding, estimated or other similar tax, duty, or other charge or assessment in the nature of a tax or deficiencies thereof (including amounts imposed for failure to file or provide correct or timely information to any Governmental Authority or third parties) and any interest, penalties (including promoter penalties), additions to tax and additional amounts imposed, whether disputed or not, and including any obligations to indemnify or otherwise assume or succeed to the Tax liability of any other Person.

“Tax Return” shall mean any return, declaration, report, election, disclosure, form, estimated return and information statement relating to Taxes, including any schedule or attachment thereto, and including any amendment thereof.

“TCA” shall mean the Taxes Consolidation Act 1997, as amended.

“the knowledge of” a Party shall mean, with respect to Seller, the knowledge of Damien Burke, Bill Murphy and Ann Marie Slattery after conducting a due inquiry.

“Title Leases” means lease dated 3 March 2017 between Industrial Development Agency (Ireland) and Seller for a term of 999 years (in respect of the property now comprised in Folio 6899L County Waterford) and lease dated 3 March 2017 between Industrial Development Agency (Ireland) and Seller for a term of 999 years (in respect of the property now comprised in Folio 6900L County Waterford).

“Third-Party Claim” shall have the meaning set forth in Section 9.5(e)(i).

“Transaction Documents” shall mean this Agreement, the Assignment and Assumption Agreement, the Contract for Sale, the Transfer, the Transition Services Agreement, the certificates and documents contemplated by Sections 7.2(c), 7.3(c) and 7.3(d) and all other documents to be executed in connection with the transactions contemplated by this Agreement.

“Transfer” shall mean the deed of assurance substantially in the form attached hereto as Exhibit G.

“Transfer Taxes” shall have the meaning set forth in Section 6.8(a).

“Transferred Assets” shall mean the Assets set forth in Exhibit C.

“Transferred Books and Records” shall mean originals and all copies of all Books and Records primarily used in connection with the Transferred Assets or otherwise in the Business, including as defined in Exhibit C.

“Transferred Contracts” shall have the meaning set forth in Exhibit C.

“Transferred Employees” shall mean Business Employees whose employment is automatically transferred to the Purchaser or its designated Affiliate in connection with the transactions contemplated hereby under TUPE but excluding any employee who has rejected or opted out of automatic transfer under TUPE.

“Transferred IP” shall have the meaning set forth in Exhibit C.

“Transferred Liabilities” shall mean the Liabilities set forth in Exhibit D.

“Transferred Personal Property” shall have the meaning set forth in Exhibit C.

“Transition Services Agreement” shall have the meaning set forth in the Recitals.

“TUPE” shall mean the Transfer of Undertakings (Protection of Employment) Regulations 2003 or predecessor or amending legislation thereto.

“VAT” shall mean value added tax as provided for in and appropriately charged in accordance with the Value-Added Tax Consolidation Act 2010 and legislation (whether delegated or otherwise) supplemental thereto or in any primary or subordinate legislation promulgated by the European Union and

any tax similar or equivalent to value added tax imposed by any country other than Ireland and any similar or turnover tax replacing or introduced in addition to any of the same.

“VAT Act” shall mean the Value-Added Tax Consolidation Act 2010 and all associated regulations.

1.2 Rules of Construction.

(a) The Parties have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Agreement.

(b) The words “hereof,” “herein,” and “hereunder” and words of similar import when used in this Agreement, will refer to this Agreement as a whole (including any annexes, exhibits and schedules to this Agreement) and not to any particular provision of this Agreement, and recital, article, section, subsection, exhibit, annex and schedule references are to this Agreement unless otherwise specified. The exhibits, annexes and schedules to this Agreement are hereby incorporated and made a part hereof and are an integral part of this Agreement. The words “include,” “including” or “includes” when used herein shall be deemed in each case to be followed by the words “without limitation” or words having similar import. The word “extent” in the phrase “to the extent” means the degree to which a thing extends, and does not simply mean “if”. The headings and table of contents in this Agreement are included for convenience of reference only and will not limit or otherwise affect the meaning or interpretation of this Agreement. The meanings given to terms defined herein will be equally applicable to both the singular and plural forms of such terms. The use of “Affiliates” and “Subsidiaries” shall be deemed to be followed by the words “as such entities exist as of the relevant date of determination”. Any reference to “days” means calendar days unless Business Days are expressly specified. When calculating the period of time before which, within which or following which any act is to be done or step taken pursuant to this Agreement, the date that is the reference date in calculating such period shall be excluded. If the last day of such period is a non-Business Day, the period in question shall end on the next succeeding Business Day. Any reference in this Agreement to gender shall include all genders, and words imparting the singular number only shall include the plural and vice versa. The word “or” is not exclusive, unless the context otherwise requires. Any reference to any document being “made available” or “delivered” by Seller to Purchaser means that Seller (a) delivered such document to Purchaser or (b) posted such document in the Data Room, in each case, as of 5:00 p.m. Central Time on the date that is two (2) Business Days prior to the date hereof. A reference to a statute, listing rule, regulation, order or other applicable law includes a reference to the corresponding regulations and instruments and includes a reference to each of them as amended, consolidated, recreated, replaced or rewritten.

(c) Any reference in this Agreement to a specific Irish legal term or specific US legal term for any action, remedy, method or form of judicial proceeding, legal document, legal status, court, official or any other legal concept, or thing will, in respect of any jurisdiction outside of Ireland or the United States of America, as

applicable, relevant to the transactions contemplated by this Agreement, be deemed to include a reference to the corresponding or most similar legal term in that jurisdiction.

ARTICLE II PURCHASE AND SALE; ASSUMPTION OF LIABILITIES

2.1 Purchase and Sale of the Transferred Assets.

Upon the terms and subject to the conditions set forth in this Agreement and the Contract for Sale (in respect of the Property only), at the Closing, each of Parent and Seller agrees to, and agrees to cause all of the other members of Seller Group to, sell, assign, transfer, convey and deliver to Purchaser (or one or more of its Affiliates, in Purchaser's sole discretion) or procure the novation to Purchaser (or one or more of its Affiliates, in Purchaser's sole discretion) and Purchaser (or one or more of its Affiliates, in Purchaser's sole discretion) agrees to purchase, acquire and accept from, as applicable, Seller and each such other member of Seller Group, all of Seller's and such other Seller Group member's respective right, title and interest in and to the Transferred Assets, free and clear of all Liens and together with all rights attached to them at the date of this Agreement or subsequently becoming attached to them. To the extent permitted by applicable Laws, title to the Transferred Assets which are capable of passing by delivery shall pass by delivery at the Closing and not pursuant to any term of this Agreement or any other document.

2.2 Transferred Liabilities; Retention by Seller of Excluded Liabilities.

(a) Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Purchaser (or one of its Affiliates) shall assume, pay, perform and discharge when due all of the Transferred Liabilities.

(b) Any other provision of this Agreement notwithstanding, Purchaser (or any of its Affiliates) shall not be obligated to assume, pay, perform, discharge or be responsible for any of the Excluded Liabilities.

2.3 Consent to Assignment.

(a) Notwithstanding anything in this Agreement to the contrary, but subject to Section 6.3, this Agreement shall not constitute a sale, assignment, transfer, conveyance or delivery of any Transferred Asset (including any Contract or Permit or any claim, right or benefit arising thereunder or resulting therefrom, in each case, included in the Transferred Assets) if any attempted sale, assignment, transfer, conveyance or delivery of such Transferred Asset (i) would constitute a breach or violation of any applicable Law (whether by operation of law or otherwise), (ii) would adversely affect the rights of Purchaser and its Affiliates thereunder or (iii) if such Transferred Asset cannot be sold, assigned, transferred, conveyed or delivered without any Consent that has not been obtained (or does not remain in full force and effect at) the Closing (any such Transferred Asset, a "Deferred Asset"), unless and until (A) such Deferred Asset can be sold, assigned, transferred, conveyed or delivered in accordance with Section 2.1 without such breach, violation of Law or adverse effect on Purchaser's rights thereunder or (B) such Consent is obtained at or prior to Closing (and remains in full force and effect at the Closing), at which time, in the case of clauses (A) and (B), and without the payment of any further consideration by any Person, such Deferred Asset and related Transferred Liability shall be deemed to be sold, assigned, transferred, conveyed or delivered in

accordance with Section 2.1 and assumed in accordance with Section 2.3(a) and shall cease to be a Deferred Asset. With respect to any such Deferred Asset, (A) from the Closing Date to the twelve (12)-month anniversary thereof, Seller and Purchaser shall, and shall cause their respective Affiliates to, reasonably cooperate and use commercially reasonable efforts to obtain, or cause to be obtained, all Consents required to assign or transfer such Deferred Asset to Purchaser (or its Affiliate) and (B) upon obtaining the requisite Consents, Seller shall sell, assign, transfer, convey and deliver all rights associated with such Deferred Asset to Purchaser (or its Affiliate), in each case, without the payment of any further consideration by any Person or agreement by any Person to any amendments, modifications or waivers of any terms of any Deferred Assets that would adversely affect the rights of Purchaser and its Affiliates thereunder in order to obtain such Consents. Subject to Section 6.3, neither Seller nor any of its Affiliates shall have any liability for failure to obtain any Consent (provided that Seller has complied with its obligations under this Section 2.3) and neither Seller, Purchaser nor their respective Affiliates (or any of their respective designees) shall be obligated to pay (or cause to be paid) (x) fees, costs or expenses in connection with such Consents (other than immaterial administrative or legal costs and expenses) or (y) any consideration to any third party with respect to such Consents.

(b) To the extent and during the period any Transferred Asset remains a Deferred Asset, and without further consideration (i) Seller shall use commercially reasonable efforts to provide Purchaser and its Affiliates (and their respective designees) the maximum allowable use of the Deferred Asset (which shall include, at a minimum, the economic benefits of such Deferred Asset), and Seller and Purchaser shall reasonably cooperate to establish an agency type or other similar arrangement reasonably satisfactory to Purchaser under which Purchaser, its Affiliates and their respective designees would obtain, to the fullest extent practicable, the applicable Deferred Assets and assume the applicable Transferred Liabilities arising thereunder or resulting therefrom in accordance with this Agreement (including by means of any subcontracting, sublicensing or subleasing arrangement) and (ii) to the extent permitted by applicable Law, Seller shall, and shall cause its Affiliates to, exercise, enforce and exploit, only at the direction of and for the benefit of Purchaser (and at the cost of the Purchaser), any and all claims, rights and benefits of Seller or its Affiliates arising in connection with such Deferred Asset. During such period and without further consideration, (A) Seller shall promptly (and in any event, within ten (10) Business Days) pay, assign and remit to Purchaser when received all monies and other consideration received by it or its Affiliates under any Deferred Asset or any claim, right or benefit arising thereunder and (B) Purchaser shall promptly pay, perform or discharge when actually due any Transferred Liability arising thereunder.

ARTICLE III PURCHASE PRICE AND ADJUSTMENTS

3.1 Purchase Price.

The purchase price in respect of the purchase and sale transactions hereunder shall be (i) \$65,000,000.00 *less* Accrued PTO Amount and (ii) the assumption of the Transferred Liabilities, which comprises the respective purchase price to be paid for the Transferred Assets (the “Purchase Price”).

3.2 Allocation of Purchase Price.

Purchaser shall determine the allocation of the Purchase Price among the Transferred Assets, which allocation may be amended from time to time (the "Purchase Price Allocation") and shall deliver to Seller a copy of the Purchase Price Allocation at or prior to Closing for informational purposes only. Seller and Purchaser agree that the Purchase Price Allocation may be adjusted by Purchaser within 12 months after the Closing if required for Purchaser's accounting compliance; *provided* that (a) Purchaser shall provide prompt notice to Seller of any such adjustment to the Purchase Price Allocation and (b) such adjusted Purchase Price Allocation shall not be binding upon Seller for Tax reporting purposes.

3.3 Withholding.

Purchaser, Seller, their respective Affiliates and any other applicable withholding agent shall be entitled to withhold, or cause to be withheld, from any payment made pursuant to this Agreement such amounts as are required to be withheld under applicable Tax Law (including any amounts required to be withheld in the event that a CGT Clearance Certificate is not produced by Seller indicating that Irish Tax is not required to be deducted from the Purchase Price); To the extent that such amounts are so withheld and paid over to the proper Governmental Authority, such withheld and deducted amounts will be treated for all purposes of this Agreement as having been paid to the applicable Party in respect of which such deduction and withholding was made. Upon either Party's reasonable written request, the other Party shall submit a tax payment certificate or other documentation (or copy thereof), to the extent issued by the applicable Governmental Authority, certifying payment of such amount.

ARTICLE IV REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Purchaser, subject to the disclosures and exceptions set forth in the disclosure schedules delivered by Seller to Purchaser concurrently herewith (the "Disclosure Schedules"), as follows:

4.1 Corporate Existence and Solvency.

(a) Seller is duly organized, validly existing and incorporated under the laws of its jurisdiction of organization. Seller has the requisite corporate, limited liability company, partnership or similar power and authority to own, lease and operate its properties, rights and assets related to the Business (including the Transferred Assets) and to conduct the Business as the same is now being conducted by it.

(b) Seller has not ceased payment of any debt nor is Seller insolvent or unable to pay its debts within the meaning of section 509 or 570 of the Companies Act. No compromise or arrangement (pursuant to under section 453 or section 676 of the Companies Act or otherwise) with any of its creditors or any class of its creditors has been entered into or proposed with respect to Seller. No receiver or manager or similar officer has been appointed over, or taken possession of, the whole or any part of the assets or undertaking of the Seller. No examiner or interim examiner is, or has been, appointed to the Seller and there is no petition pending or threatened in respect of such an appointment. No distress, execution or other process has been levied in respect of the Seller which remains undischarged and there is no unfulfilled or unsatisfied judgment or court order outstanding against the Seller.

4.2 Corporate Authority.

This Agreement and the other Transaction Documents to which Seller is a party and the consummation of the transactions contemplated hereby and thereby have been duly and validly authorized by Seller, and will be duly and validly authorized by Seller, in each case, by all requisite shareholder, corporate, partnership or similar action prior to Closing and no other proceedings on the part of Seller or its equityholders are (and no other proceedings on the part of Seller or any of its equityholders will be) necessary for Seller to authorize the execution or delivery of this Agreement or any of the other Transaction Documents or to perform any of their obligations hereunder or thereunder. Seller has, and will have at or prior to the Closing, full shareholder, corporate, limited liability company, partnership or similar organizational (as applicable) power and authority to execute and deliver the other Transaction Documents to which it is a party and to perform its obligations hereunder or thereunder. This Agreement has been duly executed and delivered by Seller, and the other Transaction Documents will be duly executed and delivered by Seller, and this Agreement constitutes, and the other Transaction Documents when so executed and delivered will constitute, a valid and legally binding obligation of Seller enforceable against it in accordance with its terms.

4.3 No Conflicts; Governmental Approvals and Consents.

(a) The execution and delivery of this Agreement and the other Transaction Documents by Seller, the performance by Seller of its obligations hereunder and thereunder and the consummation by Seller of the transactions contemplated hereby and thereby do not and will not (A) violate or conflict with any provision of the respective certificate of incorporation or by-laws or similar organizational documents of Seller, (B) result in any violation or breach of, or constitute any default (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any obligation or a loss of a benefit under, any Transferred Contract, (C) result in the creation of any Lien (except for any Permitted Lien) upon, or (D) violate, conflict with or result in any breach under any provision of any Law or Order applicable to Seller (to the extent it relates to the transactions contemplated by this Agreement), the Business or the Transferred Assets, except, in the case of clauses (B), (C) and (D), to the extent that any such breach, default, termination, cancellation, acceleration, loss, Lien, violation, conflict, breach or loss would not be material to the Business and/or the Transferred Assets, taken as a whole.

(b) No Consent, order, or license from, notice to or registration, declaration or filing with, any Ireland, European Union, United States, supranational or foreign, federal, state, provincial, municipal or local government agency, court of competent jurisdiction, administrative agency or commission or other governmental or regulatory authority or instrumentality ("Governmental Authority"), is required on the part of Seller in connection with the execution, delivery or performance of this Agreement or any of the other Transaction Documents or the consummation of the transactions contemplated hereby and thereby, except for (a) such Consents, orders, licenses, filings or notices that have been or will be obtained as of the Closing Date and remain in full force and effect, and (b) those with respect to which the failure to have been so obtained or to remain in full force and effect would not be material to the Business and/or the Transferred Assets, taken as a whole.

4.4 Sufficiency of Assets.

Except (i) for services and other rights that are to be made available pursuant to the Transition Services Agreement and the other Transaction Documents and (ii) as set forth in Section 4.4 of the Disclosure Schedules, the Transferred Assets collectively constitute all of the assets, properties and rights of the Seller Group that are necessary for, or used in connection with, the conduct of the Business as currently conducted, and in carrying on the Business, Seller does not depend on any assets owned, or services provided, by any member of the Seller Group which will not be transferred to Purchaser on Closing.

4.5 Title to Transferred Assets.

For the purpose of the representations and warranties set out in this section 4.5 only, the definition of “Transferred Assets” shall be amended and interpreted as excluding the Property and the Facility.

(a) Seller has, or at the Closing will have, and Purchaser will at the Closing acquire, full legal and beneficial ownership and good and marketable title to, or have valid and enforceable rights to use the Transferred Assets, in all cases, free and clear of all Liens, except Permitted Liens. Except for Permitted Liens, no Person, other than Seller, has any interest in the Business or any Transferred Assets.

(b) The buildings, improvements, machinery, equipment, personal properties, and other tangible assets included in Transferred Assets (i) are adequate to conduct the Business as currently conducted and for the conduct of sterile fill finish of biologic pharmaceutical products (ii) are operated in material conformity with all applicable Laws, (iii) are in reasonably good operating condition and repair (normal wear and tear excepted) without the need for material upgrade or replacement within the next twelve months, and (v) have been maintained in accordance with the normal practice of the Seller and do not require any deferred maintenance or maintenance outside the ordinary course of business.

(c) Seller has not acquired or agreed to acquire any Transferred Asset on terms that title does not pass to Seller until full payment is made. The Transferred Assets are in the possession and control of Seller and are sited within Ireland.

4.6 Real Estate.

(a) The Seller has Good and Marketable Title to the Property and title free and clear of all Liens save as specified in Section 4.6(a) of the Disclosure Schedule. Title to the Property is registered in the Property Registration Authority of Ireland with absolute leasehold title held under the Title Leases.

(b) All original deeds and documents necessary to prove title to the Property are in the possession of the Seller or held by AIB and subject to release to Seller on repayment of the AIB Loan. All deeds, documents and information supplied to the Purchaser for the purpose of deducing title to the Property in connection with this Agreement are true, complete and accurate in all material respects.

(c) All covenants, obligations, conditions, agreements and restrictions of whatever nature howsoever arising affecting the Property, including those contained in the Title Leases, have been duly performed and observed and the Seller has

not received notice of any outstanding or alleged breach or failure to perform any such covenant, obligation, condition, agreement or restriction, and, to the knowledge of the Seller, there are no circumstances which may lead to any such notice being served.

(d) The Seller is entitled to and is in possession and exclusive occupation of the Property and no other party is entitled to or is in possession or occupation or has any interest of whatever nature howsoever arising in any part of the Property and the Property is not affected by or the subject of any occupational lease, tenancy, license, agreement or arrangement relating to the occupation or use of the Property by any person other than the Seller.

(e) All rates and outgoings of whatever nature in respect of the Property incurred, or to be incurred, at or prior to Closing have been paid and will be paid by the Seller in full on the due dates for payment.

(f) There is appurtenant to the Property all rights, easements and facilities necessary for their present use and continued enjoyment and no person is entitled or, to the knowledge of Seller, has threatened to terminate, curtail or interrupt any such rights, easements or facilities.

(g) The Property is not affected by any exception, reservation, stipulation, restriction, burden, inhibition, covenant, obligation, condition, easement, quasi-easement, profit-à-prendre, license, wayleave, right or privilege of whatever nature howsoever arising which is of an unusual or onerous nature or which conflicts with or adversely affects the present use of the Property or which adversely affects the title to or value of any of the Property and there is no agreement or commitment to give or create any of the foregoing and, to the knowledge of the Seller, no person has claimed to be entitled to any of the foregoing.

(h) All buildings and other structures on or under the Property are in good and substantial repair and condition, fit for the purposes for which they are presently used, and, to the knowledge of the Seller, free from latent defects other than such defects as do not interfere with the present use thereof.

(i) The Property is served by utilities (including water, drainage, electricity gas, sewer, fibre and telecoms), all of which are connected to the public mains by media located entirely on, in or under the Property and Folio WD19982F.

(j) The Seller has delivered to Purchaser copies of all building condition, inspection, zoning, assessments, reports and other documents that relate to the condition of the Property.

(k) Without limiting the generality of the foregoing, with respect to the Property:

(i) to the extent that the Property does not directly abut a public road in charge, the Property has the benefit of a right of access and egress over third party lands to and from a public road; and

(ii) the Property has the benefit of car parking space available for use in connection with the permitted use and enjoyment of the Property.

(l) None of the improvements completed by or on behalf of the Seller with respect to the Property are in material violation of any use or occupancy restriction, limitation, condition or covenant of record or any applicable zoning or building Law or public utility or other easement or the terms of the Property, and, there are no violations of any applicable zoning or building Law relating to such improvements that remains unresolved.

(m) The Seller has not received, any notice that either the whole or any portion of any of the Property is to be condemned, requisitioned or otherwise taken by any public authority and Seller has not received any notice of any public improvements that may result in special assessments against or otherwise adversely affect the Property.

(n) Each development carried out to or on the Property since March 3, 2017 complies in all material respects with all applicable Laws relating to the planning, development and construction of buildings and all regulations made thereunder and all permissions and consents required thereunder have been duly obtained and are in full force and effect and all conditions attaching thereto have been complied with in all material respects and there are, to the Seller's knowledge, no circumstances which may lead to the withdrawal or revocation of any such permission or consent. To the knowledge of the Seller, there is no breach or default which would result in the termination or suspension of access to the Property or discontinuation of necessary sewer, water, electrical, gas, telephone or other utilities or services.

(o) There is no outstanding, or to the knowledge of Seller, threatened notice, order or certificate (whether issued under or pursuant to any statute or regulation or otherwise howsoever arising) in relation to or affecting the Property (including any condemnation, closing order, demolition order, clearance order, special amenity order, preservation order, conservation order, enforcement notice, derelict site notice, improvement notice, or prohibition notice) or any notice relating to the Property or the use of the Property under any statute or statutory rule, order or statutory instrument and, to the knowledge of the Seller, there are no circumstances as of the date hereof which would give rise to any such notice, order or certificate.

(p) To the knowledge of the Seller, there are no general contractors, architects or engineers involved with the planning, development or construction of the Property since March 3, 2017 other than those disclosed in writing to the Purchaser prior to the date of this Agreement.

4.7 Transferred Contracts.

(a) Section 4.7 of the Disclosure Schedules lists each of the Transferred Contracts.

(b) Seller has delivered to Purchaser true, correct and complete copies of each of the Transferred Contracts, together with any material amendments, modifications or supplements thereto. (i) Each Transferred Contract is in full force and

effect and is a valid and binding agreement of the Seller, and, to the knowledge of Seller, enforceable in accordance with its terms, (ii) the Seller is not in material breach of or material default under any Transferred Contract to which it is a party, and, to the knowledge of Seller, no other party to any such Contract is in material breach thereof or default thereunder, (iii) the Seller has not received, to the knowledge of Seller, no other member of the Seller Group has received, from any counterparty any notice of termination or notice or claim of default by the Seller under any Transferred Contract and (iv) to the knowledge of Seller, no event has occurred that, with or without notice or lapse of time or both, would result in a material breach or material default under any Transferred Contract by the Seller.

4.8 Litigation.

The Seller is not subject to any Order or stipulation of any Governmental Authority that would prevent or reasonably be expected to interfere with or delay the consummation of the transactions contemplated by the Transaction Documents or, would be material to the Business, and/or the Transferred Assets. There are no Proceedings pending or, to the knowledge of Seller, investigations or threatened Proceedings against Seller in respect of the Business or the Transferred Assets which (a) would be material to the Business and/or the Transferred Assets, (b) would prevent or reasonably be expected to interfere with or delay the consummation of the transactions contemplated by the Transaction Documents, (c) seek or threaten injunctive or non-monetary relief or (d) allege criminal wrongdoing or could result in a criminal penalty.

4.9 Compliance with Laws; Permits; Regulatory Compliance.

(a) Except for non-compliance or violations that would not be material to the Seller's business (other than the Excluded Business), and/or the Transferred Assets, taken as a whole, (i) the Seller's business has been conducted and the Facility has been operated in compliance with all Laws or Orders applicable to the Business, and (ii) the Seller has not received, and to the knowledge of Seller, no other member of Seller Group has received, any written notice of any violation or alleged violation by the Business of any such Law or Order.

(b) (i) The Permits listed on Section 4.9(b) of the Disclosure Schedule constitute all Permits that are necessary to conduct the Business as currently conducted, (ii) all such Permits are in full force and effect, (iii) the Business is not being conducted in violation or default of such Permits, (iv) the Seller is not in receipt of any written notification that any Governmental Authority is threatening to revoke any such Permit and (v) all such Permits were lawfully obtained, other than, in each of the foregoing clauses (i) through (v), any exceptions as would not be material to the Business and/or the Transferred Assets, taken as a whole.

(c) The operations of the Facility and Business as currently conducted are in compliance, in all material respects, with all applicable Laws. There are no, and there have been in the last three years no, recalls, corrective actions, or seizures initiated or other adverse regulatory actions taken by the Irish Health Products Regulatory Authority ("IHPRA") or any other Governmental Authority with respect to the Facility. There has been no material deficiencies, material risks or any area requiring material improvement identified in any investigation or inspection of the Facility. Seller has made

available to Purchaser all material communications with the IHPRA relating to Seller's proposed sterile fill finish operations in the Facility, the licensing of the Facility for sterile fill finish and scheduling of IHPRA inspections in connection with such licensure or otherwise.

(d) Seller has not, and to the Seller's knowledge, none of its representatives has, committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for the United States Food and Drug Administration to invoke its policy with respect to "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or for any other Governmental Authority to invoke any comparable laws. Neither Seller nor any of the Business Employees has been convicted of any crime or engaged in any conduct that would reasonably be expected to result, or has resulted, in (i) debarment under United States 21 U.S.C. Section 335a or any similar Law, or (ii) exclusion under United States 42 U.S.C. Section 1320a-7 or any similar Law.

(e) All filings with and submissions to any Governmental Authority in any jurisdiction made by the Seller with regard to its Facility or the manufacturing operations of the Business whether oral, written, or electronically delivered, were true, accurate and complete in all material respects as of the date made and, to the extent required to be updated, as so updated remain true, accurate and complete in all material respects as of the date hereof, and do not materially misstate any of the statements or information included therein, or omit to state a material fact necessary to make the statements therein not misleading. The Seller has not made an untrue statement of a material fact or fraudulent statement to any Governmental Authority or failed to disclose a material fact required to be disclosed to the Governmental Authority with respect to the Business.

(f) During the past three years, the Seller with respect to the Business has received the audits or inspections by the IHPRA or any other Governmental Authority set forth on Section 4.9(f) of the Disclosure Schedule and the Seller has made available to Purchaser all notices and material documentation relating to the results of such audits or inspections. The Seller has not received any notice of adverse finding, warning letters, untitled letters or other correspondence or notice from the IHPRA or any other Governmental Authority, alleging or asserting material noncompliance with any applicable Laws or any Permits required by any applicable Laws.

4.10 Anti-Corruption; International Trade.

(a) Since January 1, 2018, neither the Business, nor any of its officers, directors, or employees, nor, to the knowledge of Seller, any of their respective agents or third-party representatives (acting on Seller's behalf) in connection with the Business (i) has made, authorized, solicited or received any bribe, unlawful rebate, payoff, influence payment, or kickback, (ii) has established or maintained, or is maintaining, any unlawful fund of corporate monies or properties, (iii) has used or is using any corporate funds for any illegal contributions, gifts, entertainment, hospitality, travel, or other unlawful expenses, (iv) has violated or is violating in any respect Anti-Corruption Laws, or (v) has, directly or indirectly, made, offered, authorized, facilitated,

or promised any payment, contribution, gift, entertainment, bribe, rebate, kickback, financial or other advantage, or anything else of value, regardless of form or amount, to any governmental official or any other Person, in each case of the foregoing clauses (i) - (v), in connection with or relating to the Business.

(b) Neither the Business, nor any of its officers, directors, or employees, nor, to the knowledge of Seller, any of their respective agents or third-party representatives (acting on Seller's behalf) in connection with the Business is currently or has been: (i) a Sanctioned Person; (ii) operating in, organized in, conducting business with, or otherwise engaging in dealings with or for the benefit of any Sanctioned Person or in any Sanctioned Country; or (iii) otherwise in violation of any Sanctions.

(c) The Seller has implemented and maintains in effect written policies, procedures and internal controls, including an internal accounting controls system, that are reasonably designed to prevent, deter and detect violations of applicable Anti-Corruption Laws and Sanctions. The Seller has not received from any Governmental Authority any notice, inquiry, or internal or external allegation; or made any voluntary or involuntary disclosure to a Governmental Authority, in each case, concerning any actual or potential violation or wrongdoing related to Sanctions or Anti-Corruption Laws, in each case, except as would not, individually or in the aggregate be material to the Business.

4.11 Intellectual Property.

(a) Seller is the sole and exclusive legal and beneficial owner of all Transferred IP, free and clear of any Liens (other than Permitted Liens). Without limiting the generality of the foregoing, Seller has entered into binding, written Contracts with every current and former employee and/or independent contractor of the Business who was involved in the creation of the Transferred IP whereby such employees and independent contractors (i) assign to Seller any ownership interest and right they may have in any Intellectual Property created or developed by such employees or independent contractors within the scope of or during their services for the Business, and (ii) acknowledge Seller's sole and exclusive ownership of such Intellectual Property.

(b) There is no written notice, claim, indemnification request or Proceeding (including any oppositions, interferences or re-examinations) pending or, to the knowledge of Seller, threatened against Seller (i) asserting or suggesting that any infringement, misappropriation, violation, dilution or unauthorized use of Intellectual Property is or may be occurring or has or may have occurred, in each case, relating to the Business or (ii) challenging the validity, enforceability or use of any Transferred IP. The Seller has not received any written request that Seller consider taking a license under any Intellectual Property owned by a third party that relate to the Business. The conduct of the Business does not infringe, misappropriate, dilute or violate any Intellectual Property of any third party in any material respect. To the knowledge of Seller, no third party is infringing, misappropriating, diluting or violating any Transferred IP in any material respect.

(c) No Transferred IP is subject to any outstanding Order or stipulation that (i) materially conflicts with the use and distribution thereof in connection

with the Business as currently conducted or (ii) would otherwise restrict or limit Purchaser's ability to assign, transfer or license such Transferred IP.

(d) Seller has implemented reasonable policies and procedures and has taken reasonable steps necessary to maintain, enforce and protect its rights in the Transferred IP and at all times has maintained the confidentiality of all Trade Secrets included in the Transferred IP. None of the Trade Secrets or other confidential information included in the Transferred Assets have been disclosed to a third party other than employees, suppliers, representatives, customers or agents of the Business all of whom are bound by confidentiality obligations.

(e) After the Closing, Purchaser and its Affiliates will not be obligated to grant a license, covenant or similar right to a third party with respect to their own Intellectual Property, solely due to the assumption of one or more of the Transferred Contracts.

(f) The Seller is not participating in any industry standards organization that in any manner restricts or requires the licensing or enforcement of any Transferred IP to or against third parties.

(g) The Business Software listed in Section 4.11(g) of the Disclosure Schedule is in the operation of the Business. Except for the custom software identified on 4.11(g), which is included in the Transferred Assets, all of the Business Software is available for license on commercial terms from third parties.

(h) The Seller is in material compliance with all licenses to Publicly Available Software used in the Business, and no Publicly Available Software has been used in the Business in a manner that subjects, in whole or in part, the Transferred IP to any Hereditary License. Seller has not received any notice from a third party that it is in breach of any license with respect to Publicly Available Software used in the Business.

(i) Seller has implemented and maintained (or, where applicable, has required its vendors to maintain), materially consistent with commercially reasonable and standard industry practices and complying with its contractual obligations to other Persons in all material respects, reasonable security measures designed to protect all computers, networks, software and systems used in connection with the operation of the Business (the "Business Software"), from viruses and similar malware, and the Business Software and all confidential information, including Personal Data relating to the Business, from unauthorized physical or virtual access, use, modification, acquisition, disclosure or other misuse, including as required by applicable Laws. To the knowledge of the Seller, there has been no unauthorized access to or use of the Business Software, nor has there been any unscheduled downtime or unavailability of the Business Software due to unauthorized access to or use of Business Software either of which resulting in a material disruption of the Business.

(j) To the knowledge of the Seller, the Business Software included in the Transferred Assets does not contain any, and the Seller utilizes industry-standard anti-virus software designed to prevent the introduction of, "viruses", "worms", "timebombs", "Trojan horse", "key-locks", or any other devices created that could

disrupt or interfere with the operation of the Business Software or equipment upon which the Business Software operates, or the integrity of the data, information or signals the Business Software produces in a manner adverse to the Business. To the knowledge of the Seller, the Business Software does not include or install any spyware, adware, or other similar software that monitors the use of the Business Software or contacts any remote computer without the knowledge and express consent of the user(s) of the applicable Business Software, as applicable.

(k) Seller has adequate disaster recovery arrangements in place, including a disaster recovery policy, for the Business Software.

4.12 Privacy and Data Security.

(a) The use, storage, sharing, disclosure, dissemination, Processing and disposal of any personally identifiable information and Personal Data of the Business is in compliance in all material respects with all applicable privacy policies, terms of use, contractual obligations and applicable Laws, including GDPR.

(b) Seller maintains complete, accurate and up to date records of their Personal Data Processing activities in relation to the Business in accordance in all material respects with applicable data protection and privacy Laws, including GDPR.

(c) Seller has, in relation to the Business, issued privacy notices to, and (when necessary) has obtained consents from, all relevant Data Subjects which comply in all material respects with applicable data protection and privacy Laws.

(d) Since January 1, 2019, there have been no security breaches relating to, or violations of any security policy regarding, or any unauthorized access of, any Personal Data used by or on behalf of Seller in connection with the Business, other than those that were resolved without material cost, material liability or the duty to notify any Person. Further, Seller has:

(i) implemented appropriate technical and organizational measures designed to protect against the unauthorized or unlawful Processing of, and accidental loss of or damage to, Personal Data relating to the Business which is Processed by or on behalf of Seller and its Subsidiaries;

(ii) put in place appropriate agreements, as required by applicable data protection and privacy Laws, with all third parties Processing Personal Data on their behalf relating to the Business; and

(iii) undertaken reasonably appropriate privacy and information security due diligence on all such third parties in accordance with, applicable data protection and privacy Laws.

(e) There is no, and there has been no, written complaint to, or any audit, proceeding, claim or, to the knowledge of Seller, investigation (formal or informal) against, the Seller with respect to the Business by: (i) any private party; or (ii) any Governmental Authority, in each case with respect to the security, confidentiality, availability or integrity of information technology assets, Personal Data, or other data,

information or Intellectual Property, except for any of the foregoing that arose prior to the date of this Agreement and have been fully resolved.

4.13 Product Liability.

No product manufactured by Seller at the Facility has been the subject of a recall, Proceeding or, to the knowledge of Seller, investigation, and the Seller has not received any written assertions of same.

4.14 Tax Matters.

(a) All material Tax Returns required to be filed by Seller or otherwise with respect to the Transferred Assets have been duly and timely filed in accordance with all applicable Laws and all Taxes required to be paid by Seller or otherwise with respect to the Transferred Assets (whether or not shown on any Tax Return) have been duly and timely paid. All such Tax Returns are true, correct and complete in all respects and were filed in substantial compliance with all applicable Laws. No deficiency for any such Taxes has been asserted or assessed by a Governmental Authority against Seller which deficiency has not been paid.

(b) No dispute or claim concerning any Tax liability of Seller with respect to the Transferred Assets has been raised by any Governmental Authority and neither Seller nor its directors has knowledge of any such dispute or claim based upon personal contact with any agent of any Governmental Authority. To the knowledge of the Seller, there is no action, suit, proceeding, investigation, audit or claim pending or threatened with respect to any Taxes in connection with any Transferred Asset, and no deficiency for any such Taxes has been proposed, asserted or assessed against Seller.

(c) There are no Tax liens (other than Permitted Liens) on any of the Transferred Assets.

(d) Seller has never received any notice or inquiry from any Governmental Authority in a jurisdiction where Seller or its applicable Affiliates does not file Tax Returns to the effect that Seller is or may be subject to a Tax Return filing obligation or taxation with respect to the Transferred Assets by such jurisdiction.

(e) Seller has not granted any power of attorney with respect to any Tax matter that is currently in effect and that could have effect post-Closing with respect to the Transferred Assets (other than any power of attorney granted in the ordinary course of business, such as to a payroll provider).

4.15 Benefit Plans.

(a) Section 4.15(a) of the Disclosure Schedules sets forth a list of each material Benefit Plan.

(b) For each material Benefit Plan other than the Seller Pension Scheme, the Seller has made available to Purchaser accurate, current, and complete copies of each of the following, as applicable: (i) where the Benefit Plan has been reduced to writing, the plan document and all amendments; (ii) where the Benefit Plan

has not been reduced to writing, a written summary of all material plan terms; (iii) any trust agreements or other funding arrangements; (iv) any summary plan descriptions, summaries of material modifications, summaries of benefits and coverage, employee handbooks, and any other written communications (or a description of any oral communications); (v) actuarial valuations and reports for the three most recently completed plan years; (vi) copies of material notices, letters, or other correspondence from any Governmental Authority; and (vii) any filings under any amnesty, voluntary compliance, self-correction, or similar program sponsored by any Governmental Authority. For the Seller Pension Scheme, the Seller has made available to Purchaser accurate, current, and complete summary plan descriptions and summaries of benefits and coverage.

(c) Each Benefit Plan is and has been established, administered, and maintained, in all material respects, in accordance with its terms and in compliance with the requirements of applicable Law and any applicable Labor Contract. There are no pending claims, audits or investigations, or, to the knowledge of the Seller, claims, audits or investigations threatened against any Benefit Plan (other than routine claims for benefits made in the ordinary course) that, individually or in the aggregate, could result in the imposition of any material Liability on Purchaser or its Affiliates. After the Closing, Purchaser and its Affiliates will have no obligations or Liabilities related to any Benefit Plan, other than the Assumed Employee-Related Liabilities.

(d) Neither the execution of this Agreement nor the consummation of the transactions contemplated by this Agreement, alone or in connection with any other event (whether contingent or otherwise), will (i) except as required under applicable Law, entitle any Business Employee to treat such Business Employee's employment or engagement as having been terminated and/or entitle such Business Employee to any severance pay, unemployment compensation or any other payment or benefit, (ii) accelerate the time of payment or vesting, or increase the amount, of any compensation or benefit due to any Business Employee (other than with respect to any Business Employee (A) who has rejected or opted out of automatic transfer under TUPE or (B) whose employment does not transfer automatically to Purchaser or its Affiliates in connection with the transactions contemplated by this Agreement) or (iii) result in a change in the ownership of a substantial portion Parent's assets within the meaning of Section 280G of the U.S. Internal Revenue Code of 1986, as amended.

4.16 Labor Matters.

(a) Except as set forth on Section 4.16(a) of the Disclosure Schedules, the Seller has not been (a) a party to or bound by any collective bargaining agreement, works council agreement (including with any European Works Council or staff body or group thereof), trade union agreement, or other similar agreement (including any such agreement applicable on a national and/or industry-wide basis) (each of the foregoing, a "Labor Contract") in respect of the Business, (b) subject to a legal duty to bargain with or be party to a practice of engaging with (exclusive of any of the change-in-control-related notification and consultation obligations listed on Section 4.16(a) of the Disclosure Schedules), or in recognition of, any labor union, works council, trade union or similar employee representative group (each, an "Employee Representative") on behalf of the Business Employees; (c) to the knowledge of Seller, the object of any attempt to

organize or obtain recognition with respect to the Business Employees for collective bargaining purposes or representation by any Employee Representative, or presently operating under an expired Labor Contract; or (d) party to or subject to any actual or, to the knowledge of Seller, threatened, strike, work stoppage, picketing, boycott or similar activity in respect of the Business.

(b) Other than as set forth in Section 4.16(b) of the Disclosure Schedules, there are no other employees of Seller or any of its subsidiaries who are wholly or mainly assigned to the Business or whose transfer to Purchaser and its Affiliates is required under applicable Law.

(c) Except as set forth on Section 4.16(c) of the Disclosure Schedules and as required by any applicable Law, no consent or consultation of, requirement to provide information to, or the rendering of or receipt of an opinion or formal advice by, any Employee Representative, group of employees, or any Governmental Authority with jurisdiction over labor matters is required for Seller to enter into this Agreement or to consummate the transactions contemplated by this Agreement. Since January 1, 2019, Seller has complied in all material respects with their respective obligations to inform and/or consult which are similar to the type described in the immediately preceding sentence.

(d) Except as would not, individually or in the aggregate, be material to the Business, the Business is and has since January 1, 2019 been conducted in material compliance with all applicable Laws respecting labor, employment, fair employment practices, equal employment opportunities (including the prevention of discrimination, harassment and retaliation), terms and conditions of employment, the termination of employment, the classification of non-employee workers, contractors and consultants, wages and hours (including payment of all wages and overtime), work authorization, immigration, occupational safety and health, holiday pay, and mass layoffs and plant closings. No action, arbitration, dispute, litigation, audit, complaint, charge, inquiry, material disciplinary or grievance proceeding, or investigation by, on behalf of, or in relation to any current, former, or prospective employee of the Business, or any labor union, works council, or trade union, or otherwise relating to the labor or employment practices with respect to the Business (including for the avoidance of doubt any audit, investigation, or other proceeding conducted by any tax or revenue authority) is pending or, to the knowledge of Seller, threatened which, if adversely decided, may reasonably, individually or in the aggregate, be material to the Business.

(e) Except as set forth on Section 4.16(e) of the Disclosure Schedules, in the conduct of the Business, the Seller does not have any custom or practice of paying severance amounts over and above the statutory required minimum in the event of termination of employment, or bonus or similar annual incentive payments, whether in writing or otherwise.

4.17 Environmental Matters.

(a) Seller, in respect of the Business and the Transferred Assets, is in material compliance with all, and has not violated any, applicable Environmental Laws,

including the possession of, and the compliance with, all Permits required under Environmental Laws;

(b) there has been no storage, treatment, generation, transportation, handling, disposal (whether on-site or offsite), release (or, to the knowledge of Seller, threatened release) of Hazardous Materials at, on, under or from the Property in a manner that would reasonably be expected to give rise to material liability under any Environmental Laws in respect of the Business or the Transferred Assets;

(c) with respect to the Property there exists no: (i) underground storage tanks or associated equipment, (ii) groundwater monitoring wells, drinking water wells, production water wells, or injection wells, or (iii) landfills, surface impoundments or disposal areas;

(d) with respect to the Property, there exists no materials or fixtures containing asbestos, polychlorinated biphenyls, or radioactive materials;

(e) Seller has disposed of hazardous, biologic or medical waste in accordance with all applicable Environmental Laws and other Laws. The Facility is not contaminated with any pharmaceutical drug substance or drug product;

(f) Seller has not received any Environmental Claim relating to the Business or the Transferred Assets and, to the knowledge of Seller, there are no Environmental Claims threatened against Seller in respect of the Business or the Transferred Assets;

(g) Seller is not subject to any Order or settlement relating to compliance with Environmental Law in respect of the Business or the Transferred Assets; and

(h) Seller has not, and, to the knowledge of Seller, no other member of Seller Group has, assumed or retained by contract or by operation of law any obligation under any Environmental Law or concerning any Hazardous Materials relating to the Business or the Transferred Assets; and

(i) Seller has made available to Purchaser, copies of all environmental reports, studies, assessments, audits, sampling data and similar documents containing material information that may affect the Business, and all correspondence alleging any material violation of or liability under Environmental Laws and other written Environmental Claims, in each case, in their possession or control and relating to the Transferred Assets and/or the Business.

4.18 Affiliate Agreements.

There are no Affiliate Agreements that relate to the Business or the Transferred Assets.

4.19 Powers of Attorney.

In relation to the Business or any of the Transferred Assets, there are no powers of attorney granted by Seller or, to the knowledge of Seller, any other member of Seller Group, which are

currently in force other than to the holder of a Lien solely to facilitate its enforcement nor any other authority (express, implied or ostensible) given by Seller or such other member of Seller Group to any person to enter into any contract or commitment or do anything on its behalf other than any authority of Transferred Employees to enter into routine trading contracts in the normal course of their duties.

4.20 Business Records.

All records and information, including the Books and Records, in relation to the Business and the Transferred Assets are: (i) in the possession of Seller, under the direct control of Seller and subject to unrestricted access by Seller; (ii) true and complete in all material respects; and (iii) where applicable, up to date. Seller has an up to date plant register in relation to the Business showing a complete and accurate record of the plant owned or used by it.

4.21 Brokers and Other Advisors.

No member of the Seller Group has retained any investment banker, finder or broker who would have a valid claim for a fee, brokerage, commission or similar compensation in connection with the negotiation, execution or delivery of this Agreement or any of the other Transaction Documents or the consummation of any of the transactions contemplated hereby or thereby.

**ARTICLE V
REPRESENTATIONS AND WARRANTIES OF PURCHASER**

Purchaser represents and warrants to Seller as follows:

5.1 Corporate Existence.

Purchaser is duly organized, validly existing and validly incorporated under the Laws of Ireland. Purchaser has all requisite corporate power and authority to own, lease and operate the Transferred Assets, to assume the Transferred Liabilities.

5.2 Corporate Authority.

(a) This Agreement and the other Transaction Documents to which Purchaser is a party and the consummation of the transactions contemplated hereby and thereby involving Purchaser have been duly authorized by Purchaser by all requisite corporate action. Purchaser has all corporate power and authority to execute and deliver the Transaction Documents to which it is a party and to perform its obligations thereunder. This Agreement has been duly executed and delivered by Purchaser, and the other Transaction Documents will be duly executed and delivered by Purchaser, and this Agreement constitutes, and the other Transaction Documents when so executed and delivered will constitute, a valid and legally binding obligation of Purchaser, enforceable against it in accordance with its terms except as enforceability may be affected by bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting creditors' rights generally, general equitable principles (whether considered in a proceeding in equity or at law) and the implied covenant of good faith and fair dealing.

(b) The execution and delivery of this Agreement and the other Transaction Documents by Purchaser, the performance by Purchaser of its obligations

hereunder and thereunder and the consummation by Purchaser of the transactions contemplated hereby and thereby do not and will not (i) violate or conflict with any provision of the certificate of incorporation or by-laws or similar organizational documents of Purchaser, (ii) result in any violation or breach or constitute any default (with or without notice or lapse of time, or both) under, or give rise to a right of termination, cancellation or acceleration of any obligation or to the loss of a material benefit under, or result in the creation of any Lien under any contract, indenture, mortgage, lease, note or other agreement or instrument to which Purchaser is subject or is a party, or (iii) violate, conflict with or result in any breach under any provision of any Law applicable to Purchaser or any of its properties or assets, except, in the case of clauses (ii) and (iii), to the extent that any such default, violation, conflict, breach or loss would not reasonably be expected to have, individually or in the aggregate, a Purchaser Material Adverse Effect.

5.3 Governmental Approvals and Consents.

Except as set forth on Schedule 5.3, no Consent, approval, order or authorization of, license or permit from, notice to or registration, declaration or filing with, any Governmental Authority, is required on the part of Purchaser in connection with the execution, delivery or performance of this Agreement or any of the other Transaction Documents or the consummation of the transactions contemplated hereby and thereby except for such consents, approvals, orders or authorizations of, licenses or permits, filings or notices which have been obtained and remain in full force and effect and those with respect to which the failure to have obtained or to remain in full force and effect would not have or reasonably be expected to have, individually or in the aggregate, a Purchaser Material Adverse Effect.

5.4 Litigation.

As of the date of this Agreement, there is no Proceeding pending or, to the knowledge of Purchaser, investigation or threatened Proceeding against Purchaser or any of its Affiliates that would reasonably be expected to have, individually or in the aggregate, a Purchaser Material Adverse Effect.

5.5 Financial Capacity.

Purchaser has and will have at the Closing all funds necessary to pay and satisfy in full the obligations pursuant to this Agreement to pay (i) the Purchase Price, (ii) the Transfer Taxes and (iii) all fees and expenses of Purchaser and its Affiliates, including in connection with the transactions contemplated by this Agreement and the other Transaction Documents.

5.6 Brokers and Other Advisors.

None of Purchaser nor any of its Affiliates has retained any financial advisor, investment banker, finder or broker who would have a valid claim for a fee, brokerage, commission or similar compensation from Seller or its Affiliates in connection with the negotiation, execution or delivery of this Agreement or any of the other Transaction Documents or the consummation of any of the transactions contemplated hereby or thereby.

ARTICLE VI
AGREEMENTS OF PURCHASER AND SELLER

6.1 Conduct of the Business.

(a) During the period from the date hereof until the Closing or earlier termination of this Agreement in accordance with Article X (such period, the “Interim Period”), except (a) as expressly contemplated or required by this Agreement, (b) as consented to in writing by Purchaser, (c) as set forth in Section 6.1(a) of the Disclosure Schedules or (d) as required by applicable Law, Seller (x) shall, and shall cause Parent to, conduct the Business in all material respects in the ordinary course of business and use commercially reasonable efforts to preserve the Business intact, including existing relations and goodwill with Governmental Authorities, vendors and suppliers of the Business and Business Employees and (y) shall not, and shall cause Parent not to, to the extent relating to the Business:

(i) (A) incur, guarantee, become liable for or assume any indebtedness and/or (B) make any loan, advance or capital contribution to or investment in any Person, in each case of clauses (A) and (B), as would impose any Liability on Purchaser, its Affiliates, the Business or the Transferred Assets;

(ii) enter into or consummate any transaction involving the acquisition of the equity interests in or portion of the Transferred Assets of, or forming a joint venture or partnership with, any business or Person or any division thereof (whether by merger, consolidation, exchange of equity securities or by any other manner in a single transaction or series of related transactions);

(iii) sell, lease, license, transfer, assign, convey, abandon, allow to lapse or expire, exchange or swap, mortgage or otherwise encumber (including securitizations), or subject to any Lien (other than Permitted Liens) or otherwise dispose of any portion of the Transferred Assets;

(iv) (A) modify, amend, fail to renew or terminate any Transferred Contract, or waive, release or assign any material rights or material claims under any Transferred Contract, (B) enter into any Contract that would be a Transferred Contract if in existence as of the date hereof, or (C) enter into any Contract that (1) contains either (x) a change in control provision in favor of the other party or parties thereto or (y) an anti-assignment provision requiring consent or approval to effect the assignment of such Contract, or (2) that would require a payment to or give rise to any rights to any Person in each case of the foregoing clauses (1) and (2), in connection with the transactions contemplated hereby;

(v) except as required by any Benefit Plan: (A) increase the salary or other compensation of any Business Employee, other than in the ordinary course of business (and in no event shall such increases in the aggregate with respect to any Business Employee be in excess of 2%), (B) make any long-term incentive awards (cash or equity), pay or grant any new or additional entitlement to severance or termination pay, or grant transaction, retention, or other similar bonus to any Business Employee, (C) take any action to accelerate the vesting or payment of any compensation or benefit to

any Business Employee, (D) propose, agree to or effect any material change to any Business Employee's terms of employment or engagement, (E) terminate (other than for cause) any Business Employee or hire any individual who would become a Business Employee, or (F) transfer the employment of any individual to or from the Business;

(vi) (A) recognize any Employee Representative as the representative of any Business Employees, or (B) enter into any new or amended Labor Contract except as required by applicable Law;

(vii) initiate, settle, compromise, waive, discharge or agree to initiate, settle, compromise, waive or discharge any Proceeding, that (A) would involve the payment of monetary damages in excess of \$25,000, (B) would involve any admission of wrongdoing by the Business, or any of its directors, officers, employees or agents, including any Business Employees, (C) involves any regulatory agency or other Governmental Authority or alleged criminal wrongdoing or (D) would result in any injunctive or non-monetary relief or would impose any material restrictions or obligations on the Business;

(viii) (A) adopt or effect a plan of complete or partial liquidation, dissolution, merger, consolidation, restructuring, recapitalization or other reorganization or (B) discontinue the Business in any respect;

(ix) make material changes to any internal or posted policies and procedures with respect to data privacy and data security related to the Transferred Assets; or

(x) authorize or enter into any written agreement or otherwise make any commitment to do any of the foregoing.

Notwithstanding anything in this Section 6.1, Seller shall not be required to take any action or non-action that in the reasonable and good faith judgment of counsel to Seller would violate any Law applicable to Seller.

6.2 Investigation of Business.

During the Interim Period, and subject to applicable Laws, the terms of any confidentiality restrictions under Contracts to which a member of the Seller Group is a party as of the date hereof and Section 6.4, Purchaser shall be entitled, including through its Representatives, to have such reasonable access to the properties, businesses, operations, personnel and books and records of, or pertaining to, the Transferred Assets and the Business as it reasonably requests in connection with Purchaser's efforts to consummate the transactions contemplated by this Agreement. Any such access and examination shall be at Purchaser's expense and shall be conducted on reasonable advance written notice, during regular business hours and shall be subject to restrictions under applicable Law. Seller shall use its commercially reasonable efforts to cause the Representatives of Seller to reasonably cooperate with Purchaser and its Representatives in connection with such access and examination, and Purchaser and its Representatives shall reasonably cooperate with Seller and its respective Representatives and shall minimize any unreasonable disruption to the Business and the Retained Business. Notwithstanding anything herein to the contrary, no such access or examination shall be permitted to the extent that it would (i) unreasonably disrupt the operations of Seller or (ii) require Seller to disclose information subject to attorney-client privilege or conflict with any confidentiality or privacy obligations to which

Seller is bound solely on the basis that the disclosure of such information would, in the reasonable and good faith judgment of counsel to Seller, violate such attorney-client privilege or conflict with such confidentiality obligations or Laws; provided, however, that Seller shall promptly notify Purchaser thereof and use commercially reasonable efforts to seek alternative means to disclose such information as nearly as possible without adversely affecting such attorney-client privilege or confidentiality obligations. All requests for information made pursuant to this Section 6.2 shall be directed to an executive officer of Seller or such other person as designated by Seller.

6.3 Necessary Efforts; No Inconsistent Action.

Subject to the other terms and conditions of this Agreement, Seller and Purchaser agree to use their respective reasonable best efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary, proper or advisable under applicable Law to consummate and make effective the transactions contemplated by the Transaction Documents and to use their respective reasonable best efforts to cause the conditions to each Party's obligation to close the transactions contemplated hereby as set forth in Article VII to be satisfied, including all actions necessary to obtain all (a) all licenses, certificates, permits, approvals, clearances, expirations, waivers or terminations of applicable waiting periods, authorizations, qualifications and orders (each a "Consent") of any Person (including all required Consents under Transferred Contracts or the Title Leases), necessary or desirable in connection with the consummation of the transactions contemplated by the Transaction Documents and (b) novations of the Transferred Contracts, it being understood that (x) neither Party nor any of their respective Subsidiaries shall be required to expend any money other than for filing fees or expenses or immaterial administrative or legal costs or expenses, (y) the prior written consent of Purchaser shall be required with respect to any amendment, waiver or modification to any Transferred Contract for the purpose of obtaining any such Consent that is adverse to Purchaser or the Business and (z) in no event shall any Party be required to seek a novation of any Transferred Contract unless (1) such novation is required under applicable Law to transfer the burden and/or obligations of such Transferred Contract or (2) Purchaser reasonably expects that novating such Transferred Contract would reduce applicable Transfer Taxes (and, for the avoidance of doubt, if the parties to a Transferred Contract have agreed that such Transferred Contract is to be novated (pursuant to this clause (z) or otherwise), this Agreement shall not constitute an assignment or attempted assignment of such Transferred Contract nor shall this Agreement amount to an agreement for the sale of any interest in such contract). The Parties shall cooperate fully with each other to the extent necessary in connection with the foregoing.

6.4 Public Disclosures; Confidentiality.

(a) The Parties agree that each may issue a press release announcing the execution of this Agreement (the "Initial Press Releases"), with the content of the Initial Press Release to be approved by the other Party (which approval shall not be unreasonably withheld, conditioned or delayed). Except for the Initial Press Releases, unless otherwise required by Law or the rules and regulations of any stock exchange on which such Party's stock (or the stock of their direct or indirect holding company) is traded or quoted, no press release or other public announcement or comment pertaining to the transactions contemplated by this Agreement will be made by or on behalf of any Party or its Affiliates without the prior written approval of the other Party (which approval shall not be unreasonably withheld, conditioned or delayed). If in the judgment of either Party upon the advice of outside counsel such a press release or public announcement is required by Law or the rules or regulations of any stock exchange on which such Party's stock (or the stock of their direct or indirect holding company) is

traded, the Party intending to make such release or announcement shall to the extent practicable use commercially reasonable efforts to provide prior written notice to the other Party of the contents of such release or announcement and to allow the other Party reasonable time to comment on such release or announcement in advance of such issuance.

(b) Each of Seller and Purchaser agrees that this Agreement, the other Transaction Documents and the terms and conditions set forth herein and therein shall be kept confidential and shall not be disclosed or otherwise made available to any other Person and that copies of this Agreement and the other Transaction Document shall not be publicly filed or otherwise made available to the public, except (i) where such disclosure, availability or filing, upon the advice of outside counsel, is required by applicable Law (including the periodic reporting requirements under applicable securities laws) and only to the extent required by such Law or under the rules of any securities exchange on which the securities of Purchaser or Seller (or their direct or indirect holding company) are listed, and (ii) as otherwise agreed by each of Purchaser and Seller. In the event that any such disclosure, availability or filing is required by applicable Law, each of Purchaser and Seller agrees to use its commercially reasonable efforts to obtain “confidential treatment” or similar treatment of this Agreement and the other Transaction Documents and to redact such terms of this Agreement and the other Transaction Documents that either Seller, in the case of Purchaser, or Purchaser, in the case of Seller, shall reasonably request.

6.5 Access to Records.

(a) Exchange of Information. Save as may otherwise be required pursuant to applicable Law or in order to comply with reporting, disclosure, or filing requirements imposed on Purchaser or any of its Affiliates (including under applicable securities Laws) by a Governmental Authority having jurisdiction over the Purchaser or any of its Affiliates, Seller will, for a period of three (3) years (or, in respect of any records required to be retained under applicable Tax Laws, six (6) years) from the Closing Date, make available for inspection by Purchaser, at Purchaser’s expense, on reasonable notice during working hours any books and records relating to the Transferred Assets retained by Seller which are reasonably necessary for the operation and conduct of the Business or to comply with reporting, disclosure, or filing requirements imposed on Purchaser or any of its Affiliates (including under applicable securities or Tax Laws) by a Governmental Authority having jurisdiction over the Purchaser or any of its Affiliates. The Seller will allow Purchaser to take copies of any of the books and records reasonably required by Purchaser and shall instruct the employees, auditors and other professional advisers of Seller to provide to Purchaser all information that it may reasonably require.

(b) Ownership of Information. Any information owned by a Party that is provided to a requesting Party pursuant to this Section 6.5 shall be deemed to remain the property of the providing Party. Unless specifically set forth herein, nothing contained in this Agreement shall be construed as granting or conferring rights of license or otherwise in any such information.

(c) Record Retention. Except as required by applicable Law, and to the extent permitted by applicable data protection and privacy Law, each Party agrees to

use its reasonable commercial efforts to retain copies of the books and records relating to the Business and the Transferred Assets, in any form or media, other than Excluded Assets (the “Books and Records”) in their respective possession or control for a period of three (3) years (or, in respect of Tax related Books and Records, six (6) years), following the Closing Date.

(d) Limitation of Liability. No Party shall have any liability to any other Party in the event that any information exchanged or provided pursuant to this Section 6.5 is found to be inaccurate. No Party shall have any liability to any other Party if any information is destroyed or lost after commercially reasonable efforts by such Party to comply with the provisions of Section 6.5(c).

(e) Other Agreements Providing For Exchange of Information. The rights and obligations granted under this Section 6.5 are subject to any specific limitations, qualifications or additional provisions on the sharing, exchange or confidential treatment of information set forth in this Agreement.

(f) Confidential Information. Nothing in this Section 6.5 shall require either Party to violate any agreement with any third parties regarding the confidentiality of confidential and proprietary information; provided, however, that in the event that either Party is required under this Section 6.5 to disclose any such information, that Party shall use all commercially reasonable efforts to seek to obtain such third party’s consent to the disclosure of such information and implement requisite procedures to enable the disclosure of such information.

6.6 TUPE and Employee Benefits.

(a) TUPE to Apply.

The Seller and the Purchaser hereby acknowledge that the transfer of the Business contemplated hereby is one to which TUPE applies. The Seller and the Purchaser hereby further acknowledge that pursuant to TUPE, the contracts of employment of the Transferred Employees shall, with effect from the Closing, be transferred to the Purchaser. The Parties acknowledge that they are each required to engage in an information and consultation process with their respective employees in respect of the Purchase under TUPE and they shall each comply with all such obligations and to indemnify one another in accordance with the terms of Article IX in respect of Losses suffered by the other Party arising out of any failure to comply with such requirements.

(b) Discharge of Obligations

Each of the Seller and the Purchaser shall duly and fully discharge all of its respective obligations arising under or by virtue of TUPE and the Employees (Provision of Information and Consultation) Act 2006 in connection with the transactions contemplated hereby.

(c) Information on Employment

The Seller shall both before and after the Closing furnish to the Purchaser such evidence and information as the Purchaser may from time to time reasonably require in relation to

the discharge by the Seller of the Seller's obligations under TUPE together with such other information as the Purchaser may from time to time reasonably require to assist it in continuing the Transferred Employees' terms and conditions of employment, in so far as provided for under any contracts of employment, collective agreements and any other matters in connection therewith. The Purchaser shall before the Closing furnish to the Seller such evidence and information as the Seller may from time to time reasonably require in relation to the discharge by the Seller of the Seller's obligations under TUPE.

(d) Seller Obligations

The Seller shall perform and shall be fully liable and responsible for all obligations and Liabilities arising in respect of the period up to and including the Closing by virtue of any contracts of employment, employment relationships, collective agreements if any or enactments or statutory provisions (or orders or regulations made thereunder) in relation to the Business Employees in force at any time prior to the Closing and shall at all times fully and effectually indemnify and keep indemnified the Purchaser against all Liabilities howsoever arising under or by virtue thereof. In the event that any claim is made against the Purchaser by a Transferred Employee or a Retained Employee, in relation to any of the foregoing matters arising from circumstances taking place prior to the Closing, the Seller shall furnish to the Purchaser such evidence and information as the Purchaser may require to defend that claim or, if such claim was raised by a Transferred Employee, manage any ongoing employment relationship with the Transferred Employee.

(e) Purchaser Obligations

The Purchaser shall perform and shall be fully liable and responsible for all obligations and Liabilities arising in respect of the period immediately following the Closing by virtue of any contracts of employment, employment relationships, collective agreements if any or enactments or statutory provisions (or orders or regulations made thereunder) in relation to the Transferred Employees in force at any time from thereafter following the Closing and shall at all times fully and effectually indemnify and keep indemnified the Seller against all Liabilities howsoever arising under or by virtue thereof, save where such Liabilities can be attributed to failure by the Seller to provide any reasonably necessary or accurate information to the Purchaser to prevent any such issue arising. In the event that any claim is made against the Seller, in relation to any of the foregoing matters arising from circumstances taking place post the Closing, the Purchaser shall furnish to the Seller such evidence and information as the Seller may require to defend that claim.

(f) Notice to Transferred Employees

As soon as reasonably practicable after Closing, the Seller shall deliver to the Transferred Employees a letter, in an agreed form, between them notifying the Transferred Employees of the transfer of their employment to the Purchaser. This is in addition to the Seller's and the Purchaser's separate respective obligations to inform, and where required, consult with employee representatives in relation to the transfer of the Business as separately provided for in Section 6.6(a).

(g) Liability for Retained Employees.

Where any Retained Employee, employee or individual other than a Transferred Employee, whether an employee of the Seller and its Affiliates or not, claims to be an employee of the Purchaser or makes any other claim against the Purchaser, the Seller shall indemnify the Purchaser in respect of any Liabilities incurred by it in respect of defending or as a consequence of any such claim, to include any ongoing salary if ordered to accept any such employee into its employment, severance costs if it chooses to agree to a voluntary termination with such employee in either case during the period of one year from that person's date of transfer of employment under TUPE, regardless of when a claim is made by such person or other costs incurred in managing such claims.

(h) Post-Closing Benefit Plan Participation. From and after the Closing, Purchaser shall use commercially reasonable efforts to cause any employee benefit plans of Purchaser and its Affiliates that are made available to the Transferred Employees after the Closing ("Purchaser Plans") to take into account for purposes of eligibility and benefit accruals (other than benefit accruals under any defined benefit pension plan or as would result in a duplication of benefits), services prior to the Closing by such Transferred Employees to Seller (and any predecessors thereof that previously employed such Transferred Employees and as to which Seller recognized such years of service) as if such service were with Purchaser and its Affiliates. With respect to each Transferred Employee who elects to participate in Purchaser Plans following the Closing, and such Transferred Employee's dependents, Purchaser shall, and shall cause its applicable Affiliate to, use commercially reasonable efforts to (i) waive or cause to be waived any pre-existing condition exclusions to coverage, any evidence of insurability provisions, any active at work requirement and any waiting period or service requirements that did not exist or had been waived or otherwise satisfied under Seller's comparable medical, dental, pharmaceutical and vision benefit plans prior to the Closing and (ii) apply towards any deductible requirements and out-of-pocket maximum limits under its benefit plans applicable to the year in which the Closing occurs, any amounts paid by such Transferred Employee toward such requirements and limits under Seller's and/or Seller's Subsidiaries' benefit plans for such applicable year. For the avoidance of doubt, nothing in this Agreement or any Transaction Document shall operate to transfer the Seller Pension Scheme, to the Purchaser or otherwise make the Purchaser liable in respect of the Seller Pension Scheme.

(i) Post-Closing Maintenance of Remuneration and Benefits. The Purchaser agrees (without prejudice to its obligations pursuant to Section 6.6(b)) that, it shall, at a minimum, for the period of 12 months immediately following the Closing, in respect of each Transferred Employee who remains in employment with the Purchaser or its Affiliates, at least maintain the same base salary or wage rate, as was provided to each such Transferred Employee immediately prior to the Closing; and provide a benefits package which is, in the aggregate, not less than the value of the existing benefits available to such Transferred Employee immediately prior to the Closing.

(j) Severance Obligations. The Parties intend that the transactions contemplated by this Agreement shall not constitute a separation, termination, or severance of employment of any Transferred Employee prior to or upon the consummation of the Closing. Without limiting the provisions of this Section 6.6(i), Seller shall bear any costs related to, and shall indemnify and hold harmless Purchaser and its Affiliates from and against, any claim made against Purchaser (or Purchaser's

Affiliate) by any Business Employee for any Severance Obligations, in each case, arising out of, relating to, or in connection with any of the following: (i) any Business Employee's refusal, prior to the Closing, to accept an offer of employment from, or rejection of an automatic transfer of employment to, Purchaser (or any of its Affiliates) (save where the Business Employee's refusal to accept an offer of employment or rejection of an automatic transfer of employment to Purchaser or any of its Affiliates is primarily based on Purchaser proposing to make a material adverse change to the terms and conditions of employment of any such Business Employee without consent of such Business Employee) and (ii) any action taken by Seller or its Subsidiaries to terminate the employment of any Business Employee or individual who would otherwise have been a Business Employee but for such action or which provides such individual a right to terminate employment, including any action or omission by Seller or its Subsidiaries (x) to amend or otherwise modify, on or prior to the Closing, any terms and conditions of employment applicable to, or compensation and benefits provided to, any Business Employee or (y) that does not comply with applicable Law or the terms of any Benefit Plan. Without limiting the provisions of Section 6.6(i), Purchaser shall bear any costs related to, and shall indemnify and hold harmless Seller from and against, any claims made by any Transferred Employee for any Severance Obligations, in each case, arising out of, relating to or in connection with any of the following: (I) the failure of Purchaser or its applicable Affiliate to continue the employment of, any Transferred Employee in accordance with this Agreement or as required by applicable Law (other than, for the avoidance of doubt, as a result of any employee's rejection of an automatic transfer of employment to, Purchaser or any of its Affiliates prior to the Closing in which case they would become a Retained Employee), and (II) any Business Employee's rejection of an automatic transfer of employment to Purchaser or any of its Affiliates (and becoming a Retained Employee), which is primarily based on Purchaser proposing to make a material adverse change to the terms and conditions of employment of any such Retained Employee without consent of such Business Employee.

(i) Excluded Employee-Related Liabilities. Seller and its Subsidiaries shall remain responsible for (x) all Liabilities arising under Benefit Plans of Seller or its Subsidiaries and (y) all Liabilities with respect to (A) Business Employees that relate to the period on or prior to Closing Date (specifically including Liabilities regarding any claim in connection with equity awards, vested or unvested, and other entitlements under short or long term equity incentive plans of Seller, in each case, granted prior to Closing), whether such claims are made prior to, on, or following the Closing Date and (B) Retained Employees. Seller agrees that Purchaser shall not assume any Benefit Plan of the Seller or its Subsidiaries. For the purposes of this Agreement, all Liabilities and obligations of the Seller described in this Section 6.6(j)(i) and Sections 6.6(a), 6.6(b), 6.6(c), 6.6(d) and 6.6(f) are collectively referred to as the "Excluded Employee-Related Liabilities".

(ii) Assumed Employee-Related Liabilities. Except where the Liability arises as a result of Seller's breach of any of its obligations under this Agreement, Purchaser and its Affiliates shall be responsible for (x) all Liabilities under Purchaser or its Affiliates' benefits plans to Transferred Employees, and (y) all other Liabilities with respect to Transferred Employees that relate to the period after the Closing, including Liabilities for any claims brought by any Transferred Employees or any Governmental Authority with respect to any Transferred Employee against the Seller

or any of its Subsidiaries after Closing to the extent such claims are the result of Purchaser's failure to comply with applicable Law or Contracts in connection with the Transferred Employee's employment or the termination thereof following Closing. For the purposes of this Agreement, all Liabilities of the Purchaser described in this Section 6.6(j)(ii) and Section 6.6(e) are collectively referred to as the "Assumed Employee-Related Liabilities".

(k) Vacation. Following the Closing, Purchaser or its applicable Affiliate will honor, as to each Transferred Employee, all accrued and unpaid hours of vacation, personal hours or days earned and sick leave applicable to such Transferred Employee as of the Closing Date relating to the period through the Closing Date (the aggregate dollar amount that would be payable to such Transferred Employees if the accrued and unpaid vacation, personal hours or days and sick leave were paid in cash to such Transferred Employees as of the Closing Date based on their compensation in effect at the time of transfer of employment, the "Accrued PTO Amount").

(l) Other Accruals. No later than five (5) Business Days before the Closing Date, and with respect to Transferred Employees, Seller shall, and shall cause its Affiliates to, provide Purchaser with proper accruals regarding accrued but unpaid vacation, personal hours or days earned and sick leave as well as the Accrued PTO Amount. With the exception of Business Employees' unpaid commission and bonus amounts earned prior to the Closing Date, which shall be paid by Seller in the first payroll cycle after the Closing Date, other compensation and benefit accruals for elements such as but not limited to (i) payroll, (ii) payroll and other employer Taxes, (iii) retirement plan payables, (iv) employee stock purchase plan, (v) expenses and (vi) reimbursements (fuel, tuition or professional membership) shall be settled by Seller prior to the Closing Date.

(m) Administration. Following the date hereof and subject to applicable Law, the Parties shall reasonably cooperate in all matters reasonably necessary to effect the transactions contemplated by this Section 6.6, including exchanging information and data relating to workers' compensation, employee benefits, and employee benefit plan coverages and, in the case of Seller, making the Business Employees available during business hours to Purchaser and its Affiliates as may be reasonably requested by Purchaser or its Affiliates during the TUPE information and consultation period provided that (i) a Seller representative shall be present during any such meeting with Business Employees and (ii) talking points and script of meeting shall be agreed jointly acting reasonably in advance of any such meeting and the Purchaser and its Affiliates agree to follow the agreed form script).

(n) No Third-Party Beneficiary. This Section 6.6(n) shall be binding upon and inure solely to the benefit of each of the Parties, and nothing in this Section 6.6(n), expressed or implied, is intended to confer upon any other Person any rights or remedies of any nature whatsoever under or by reason of this Section 6.6(n). Without limiting the foregoing, no provision of this Section 6.6(n) will create any third-party beneficiary rights in any current or former employee of Seller or any Business Employees in respect of continued employment (or resumed employment) or any other matter. Nothing in this Section 6.6(n) is (i) deemed to establish, amend, or modify any Benefit Plan, Purchaser Plan or any other employee benefit plan, policy, program, agreement or

arrangement maintained or sponsored by Seller, Purchaser or their respective Affiliates or (ii) intended to interfere with Purchaser's or its Affiliates' right from and after the Closing to amend or terminate any employee benefit plan, policy, program, agreement or arrangement or the employment of any Transferred Employee, subject to applicable Law.

(o) Updated Business Employee List. Seller shall deliver to Purchaser an updated version of Section 1.1(a) of the Disclosure Schedules (the "Business Employee List") at least fifteen (15) days prior to the Closing Date. Any changes to the Business Employee List following the date hereof shall be mutually agreed to by Purchaser and Seller on or prior to the Closing Date (such agreement of either party shall not be unreasonably withheld, conditioned or delayed).

6.7 Non-Solicitation; No-Hire.

(a) From and after the Closing Date until the one year anniversary of the Closing Date, Seller covenants and agrees, that it will not, and will cause each member of the Seller Group to not, directly or indirectly, solicit for employment, hire, employ, engage or offer employment to, or seek to induce or influence to leave employment with Purchaser or any of its Affiliates, any Transferred Employee or any employee of Purchaser assigned to work at the Facility; provided, that the foregoing shall not be deemed to prohibit (i) any member of the Seller Group from engaging in general media advertising or general employment solicitation that is not targeted towards such Transferred Employees or (ii) solicitations, targeting, or hiring, employing, engaging or offering employment to, former employees of Purchaser or any of its Affiliates.

(b) From and after the Closing Date until the one year anniversary of the Closing Date, Purchaser covenants and agrees, that it will not, and will cause each member of the Purchaser Group to not, directly or indirectly, solicit for employment, hire, employ, engage or offer employment to, or seek to induce or influence to leave employment with Seller, any Restricted Employee (other than, for the avoidance of doubt, Transferred Employees); provided, that the foregoing shall not be deemed to prohibit (i) Purchaser from engaging in general media advertising or general employment solicitation that is not targeted towards such Restricted Employees or (ii) solicitations, targeting, or hiring, employing, engaging or offering employment to, former employees of Seller or any of its Affiliates. For purposes of this Section 6.7(b), "Restricted Employees" mean (i) employees of Seller who directly interface with Purchaser's employees in providing services under the Transition Services Agreement and (ii) employees of Seller who are assigned to work in the Facility or in the Excluded Business as of the Closing.

6.8 Tax Matters.

(a) Transfer Taxes. All transfer, recordation, stamp duties, excise, license, or similar fees or taxes (collectively, "Transfer Taxes") shall be borne by Purchaser. The definition of Transfer Taxes shall not include VAT which shall be dealt with in accordance with Section 6.8(b). Any Tax Returns that must be filed in connection with any Transfer Taxes shall be prepared by the Party that customarily has primary responsibility for filing such Tax Returns pursuant to the applicable Laws under and according to which the respective Tax Returns are due to be filed. Seller and

Purchaser shall reasonably cooperate, and shall cause their respective Affiliates to reasonably cooperate, with each other to make all filings, returns, reports and forms as may be required to comply with all applicable Laws relating to Transfer Taxes and to lawfully obtain any available mitigation, reduction or exemption from any Transfer Taxes.

(b) VAT. The Parties agree that the Purchase Price shall be exclusive of VAT. The Parties intend that the sale is a sale to which sections 20(2)(c) and section 26(2) of the VAT Act apply such that the sale shall be deemed not to be a supply of goods or services for the purposes of the VAT Act. The Purchaser warrants that the Purchaser is an Accountable Person as defined by Section 2(1) of the VAT Act for the purposes of section 20(2)(c) of the VAT Act. The Purchaser shall indemnify and keep the Seller indemnified against any loss, cost or liability which arises as a result of such warranty being or becoming untrue or incorrect in any respect due to the act, neglect or default of the Purchaser. To the extent that VAT is chargeable, the Purchaser will pay such VAT to the Seller as is due on the sale within ten days of the Seller providing to Purchaser a valid VAT invoice.

(c) Tax Returns and Payment of Taxes.

(i) Seller shall remit when due or cause to be remitted when due any amount of Taxes due in connection with the Transferred Assets and/or Transferred Employees for any taxable period ending prior to the Closing Date. Seller shall duly file or cause to be duly filed, any Tax Return required to be filed in respect of any Tax which it is required to pay pursuant to the immediately preceding sentence.

(ii) Purchaser shall remit when due or cause to be remitted when due any amount of Taxes due in connection with the Transferred Assets and/or Transferred Employees for any taxable period beginning on or after the Closing Date; provided, however, that for the avoidance of doubt Purchaser shall not be liable for any Excluded Liabilities. Purchaser shall duly file or cause to be duly filed, any Tax Return required to be filed in respect of any Tax which it is required to pay pursuant to the immediately preceding sentence.

(d) Cooperation and Assistance.

(i) The Parties shall make commercially reasonable efforts to cooperate with each other in the filing of any Tax Returns and the conduct of any audit or other proceeding. They each shall execute and deliver such powers of attorney and make available such other documents as are reasonably necessary to carry out the intent of this Section 6.8.

(ii) Upon request, each Party shall deliver to the other Party certified copies of all receipts for any Tax with respect to which such other Party or any of its Affiliates could claim a foreign tax credit and any supporting documents required in connection with claiming or supporting a claim for such a foreign tax credit.

(iii) The Parties shall retain records, documents, accounting data and other information in whatever form that are necessary for the preparation and filing, or for any Tax audit, of any and all Tax Returns with respect to any Taxes that

relate to taxable periods that do not begin after the Closing Date. Such retention shall be in accordance with the record retention policy of the respective Party. Each Party shall give any other Party reasonable access to all such records, documents, accounting data and other information as well as to its personnel and premises to the extent necessary for a reasonable review or a Tax audit of such Tax Returns and relevant to an obligation under this Section 6.8.

(iv) Upon request, Seller shall deliver its Irish tax reference number to the Purchaser to the extent reasonably required by Purchaser in order to make an Irish stamp duty filing in connection with the purchase of the Transferred Assets.

6.9 Mail Handling.

To the extent that Purchaser and/or any of its Subsidiaries receives any mail or packages addressed to Seller or members of the Seller Group delivered to Purchaser not relating to the Business, the Transferred Assets or the Transferred Liabilities, Purchaser shall promptly deliver such mail or packages to Seller. To the extent Seller or members of the Seller Group receives any mail or packages addressed and delivered to Seller or a member of the Seller Group but relating to the Business, the Transferred Assets or the Transferred Liabilities, Seller shall promptly deliver such mail or packages to Purchaser.

6.10 Wrong Pockets.

To the extent that following the Closing, Seller or Purchaser discover that any Asset:

(a) not intended to be transferred to Purchaser pursuant to the transactions contemplated by this Agreement and the other Transaction Documents was transferred at, prior to or after the Closing (each such Asset, a "Held Asset"), Purchaser shall, and shall cause its Affiliates to (i) promptly assign and transfer all right, title and interest in such Held Asset to Seller or its designated assignee without delivery of any incremental consideration therefor, and (ii) pending such transfer, (A) hold in trust such Held Asset and provide to Seller or its designated assignee all of the benefits associated with the ownership of the Held Asset, and (B) cause such Held Asset to be used or retained as may be reasonably instructed by Seller; and

(b) intended to be transferred to Purchaser pursuant to the transactions contemplated by this Agreement and the other Transaction Documents was not transferred at, prior to or after the Closing (each such Asset, an "Omitted Asset"), Seller shall, and shall cause its Affiliates to (i) promptly assign and transfer all right, title and interest in such Omitted Asset to Purchaser or its designated assignee without delivery of any incremental consideration therefor, and (ii) pending such transfer, (A) hold in trust such Omitted Asset and provide to Purchaser or its designated assignee all of the benefits associated with the ownership of the Omitted Asset, and (B) cause such Omitted Asset to be used or retained as may be reasonably instructed by Purchaser.

6.11 Release of Liens; Accounts Payable.

Seller shall cause the release of all Liens (other than Permitted Liens) on each Transferred Asset at or prior to the Closing and shall provide to Purchaser with a confirmation from the holder(s) of such Liens with respect to such release.

6.12 Shared Contracts.

(a) Following the date hereof, the Parties shall use reasonable efforts to enter into or to grant, and to cause each third party counterparty to a Shared Contract that is set forth in Section 6.12, of the Disclosure Schedules (each a “Specified Shared Contract”) to enter into or to grant, any new agreements, bifurcations or consents as are reasonably necessary to permit Purchaser to operate the Business on an independent basis following the Closing, derive those claims, rights and benefits, and to assume any obligations and economic burdens, as each such Person derives from such Specified Shared Contract immediately prior to the Closing (such portion of the claims, rights benefits, obligations and economic burdens that are related to the Business, is referred to herein as the “Business Portion”) and such portion of the claims, rights, benefits, obligations and economic burdens that are related to Seller and the other members of Seller Group and their respective subsidiaries and their businesses (other than the Business), is referred to herein as the “Non-Business Portion”). If, on the Closing Date, any such third party agreement, bifurcation or consent, as the case may be, is not obtained with respect to a Specified Share Contract, Seller and Purchaser shall, for a period of twelve (12) months following the Closing, (a) continue to use commercially reasonable efforts to enter into or to grant, and to cause each third party counterparty to such Specified Shared Contract to enter into or to grant, any such new agreements, bifurcations or consents, as applicable, (b) cooperate (at their own expense) reasonably and lawfully following the Closing in a mutually acceptable arrangement under which Purchaser, on the one hand, and Seller, on the other hand, would, where commercially reasonable and in compliance with applicable Law, obtain the appropriate claims, rights and benefits and assume and perform the related obligations and bear the related economic burdens of the Business Portion of such Specified Shared Contract (in the case of Purchaser) and the Non-Business Portion of such Specified Shared Contract (in the case of Seller), including by means of subcontracting, sublicensing or subleasing arrangements, or enforcement by the party to such Specified Shared Contract for the benefit (and at the expense) of Purchaser or any of its subsidiaries, or Seller that is an intended beneficiary thereof pursuant to this Section 6.12 and (c) pay, reimburse and/or otherwise be responsible for the Business Portion of all license fees payable to any licensor by any of the foregoing or their respective Subsidiaries under any such Specified Shared Contract on a pro rata basis (based on the relative proportions of such license fee attributable to the Business Portion and Non-Business Portion of such Specified Shared Contract).

(b) Notwithstanding anything else set forth in this Section 6.12, neither Party nor any of its Affiliates shall (i) be required to take any action pursuant to Section 6.12(a) that would (x) result in a violation of any obligation which such Party or its Affiliates has to any third party, (y) constitute a breach or violation of any applicable Law (whether by operation of law or otherwise), or (z) adversely affect the rights of Purchaser and its Affiliates thereunder (unless the prior written consent of Purchaser has been obtained), (ii) be obligated to pay (or cause to be paid) (x) fees, costs or expenses in connection with their obligations under Section 6.12(a) (other than immaterial administrative or legal costs and expenses) or (y) any consideration to any third party who is requested to enter into or to grant any such new agreements, bifurcations or consents, or (iii) be required to take any action in connection with any Shared Contract that is not a Specified Shared Contract.

(c) If the arrangements in Section 6.12(a) cannot be made or completed in respect of a Specified Shared Contract within the period of twelve (12) months following the Closing, at Purchaser's request, Seller may (at Seller's expense) seek to terminate the relevant Specified Shared Contract save in circumstances where material or unreasonable termination fees would apply. In the event that the Specified Shared Contract cannot be so terminated (or Purchaser does not make the request to so terminate), Seller and Purchaser shall cooperate and make such other arrangements between them, on terms reasonably satisfactory to Purchaser, as are permitted by the Specified Shared Contract to implement so far as possible the effective transfer of the benefit and burden of the Specified Shared Contract to Purchaser.

(d) No Solicitation of Business Acquisition Proposals.

During the Interim Period, Seller shall not, and shall cause its Affiliates and its and their respective Representatives not to, directly or indirectly, (i) initiate, solicit or knowingly encourage or facilitate the making or submission of any Business Acquisition Proposal, (ii) participate in any discussions or negotiations with any Person regarding a Business Acquisition Proposal (provided, that informing a Person of the existence of this Agreement after any such Person contacts Seller, any of its Affiliates or any of its or their respective Representatives regarding a Business Acquisition Proposal and of the restrictions set forth in this Section 6.12 shall not be a breach of this Section 6.12) or (iii) furnish any information to any Person with respect to, or agree to or otherwise enter into, any Business Acquisition Proposal. From and after the date hereof, Seller shall, and shall cause its Affiliates and its and their respective Representatives to, discontinue and not engage in any solicitation efforts or negotiations with respect to or in furtherance of any Business Acquisition Proposal. Seller shall promptly (and in any event within two (2) Business Days after receipt thereof by Seller, any of its Affiliates or any of its or their respective Representatives) advise Purchaser orally and in writing of any Business Acquisition Proposal, request for information with respect to any Business Acquisition Proposal or inquiry with respect to or which would reasonably be expected to result in a Business Acquisition Proposal; the material terms and conditions of such request, Business Acquisition Proposal or inquiry; and the identity of the Person making the same.

6.13 Business Materials; Transferred Personal Property.

At or prior to the Closing Date to the extent reasonably practicable, and otherwise on or promptly after the Closing Date, Seller shall, and shall cause its Affiliates to, deliver to Purchaser (or its designees) at the Facility (i), the Transferred Books and Records and (ii) the Transferred Personal Property, in each case, if and to the extent not already located at the Property or in the possession of Transferred Employees. If, at any time following the Closing, any of Seller or its Affiliates shall discover in its possession or under its control any other such Transferred Books and Records or Transferred Personal Property, Seller shall, and shall cause its Affiliates to, deliver promptly such Transferred Books and Records and/or Transferred Personal Property to Purchaser (or any of its designees).

6.14 Post-Closing Responsibilities.

From and after the Closing, Purchaser shall be responsible for the operation of the Transferred Assets, including the Facility, conducted by Purchaser or any other member of the Purchaser Group pursuant to, and in accordance with, this Agreement, and Seller will have no liability for such operations except for any liability imposed on Seller under the Transition Services Agreement.

ARTICLE VII
CONDITIONS TO CLOSING

7.1 Conditions Precedent to Obligations of Purchaser and Seller.

The respective obligations of the Parties to consummate and cause the consummation of the Purchase shall be subject to the satisfaction (or waiver, in whole or in part, by the Party for whose benefit such condition exists in its sole discretion, to the extent permitted by applicable Law) on or prior to the Closing Date of each of the following condition:

(a) No Injunction, etc. No Governmental Authority of competent jurisdiction shall have enacted, issued, promulgated, enforced or entered any Law or Order that is in effect on the Closing Date that has or would have the effect of prohibiting or enjoining the Purchase or making the transactions contemplated by this Agreement illegal.

7.2 Conditions Precedent to Obligation of Purchaser.

The obligation of Purchaser to consummate and cause the consummation of the transactions contemplated by this Agreement shall be subject to the satisfaction (or waiver, in whole or in part, by Purchaser in its sole discretion, to the extent permitted by applicable Law) on or prior to the Closing Date of each of the following conditions (provided that Purchaser will not be obliged to complete the purchase of any of the Transferred Assets unless the purchase of all the Transferred Assets is completed simultaneously):

(a) Accuracy of Representations and Warranties of Seller. (i) The representations and warranties of Seller contained in this Agreement, taken as a whole (other than Seller Fundamental Representations) (disregarding any exception or qualification of such representations and warranties that are qualified by the terms “material”, “in all material respects”, or similar words or phrases) shall be true and correct in all material respects on the Closing Date (except to the extent such representations and warranties by their terms speak as of an earlier date, in which case they shall be true and correct in all material respects as of such date), and (ii) the Seller Fundamental Representations shall be true and correct in all but de minimis respects on the Closing Date (except to the extent such representations and warranties by their terms speak as of an earlier date, in which case they shall be true and correct in all but de minimis respects as of such date)

(b) Covenants of Seller. Seller shall have performed and complied in all material respects with all covenants contained in this Agreement and the Transition Services Agreement to be performed by it prior to the Closing;

(c) Officer’s Certificate. Purchaser shall have received a certificate signed by an authorized executive officer of Seller, dated the Closing Date, to the effect that the conditions specified in Sections 7.2(a) and 7.2(b) are satisfied;

(d) Section 980 of the TCA. Seller shall have delivered to Purchaser either a CGT Clearance Certificate in respect of the Purchase Price or a letter from the auditors of the Seller addressed to (and in a form satisfactory to) Purchaser confirming that none is required;

(e) Stamp Duty. Seller shall have delivered its Irish tax reference number to Purchaser to the extent reasonably required by Purchaser in order to make an Irish stamp duty filing in connection with the purchase of the Transferred Assets;

(f) Certain Consents. The approvals, consents, novations, ratifications or waivers listed in Schedule 7.2(f) hereto, in each case in a form reasonably satisfactory to Purchaser, shall have been obtained;

(g) Employee Consultations. Seller shall have complied with its obligations under Sections 6.6(a) and 6.6(b);

(h) Facility Cleaning. Seller shall have certified to Purchaser that it completed the cleaning of the Facility in accordance with usual cleaning practices on the Facility (together with documentation of the compliance with the cleaning standards in the validated manufacturing process to the extent applicable; documentation showing how cleaning limits were set; how adequacy of cleaning was verified on equipment and the Facility surfaces; and how ductwork was protected);

(i) Release of Liens. All Liens shall have been released from the Transferred Assets, including the AIB Charges; and

(j) Closing Deliverables. Purchaser shall have received the deliverables required under Section 8.3 hereof.

7.3 Conditions Precedent to Obligation of Seller.

The obligation of Seller to consummate and cause the consummation of the Purchase shall be subject to the satisfaction (or waiver, in whole or in part, by Seller in its sole discretion, to the extent permitted by applicable Law):

(a) Accuracy of Purchaser's Representations and Warranties. (i) The representations and warranties of Purchaser contained in this Agreement (other than Purchaser Fundamental Representations) (disregarding any exception or qualification of such representations and warranties that that are qualified by the terms "material", "in all material respects", "Purchaser Material Adverse Effect", or similar words or phrases) shall be true and correct in all material respects on the Closing Date (except to the extent such representations and warranties by their terms speak as of an earlier date, in which case they shall be true and correct in all material respects as of such date), and (ii) the Purchaser Fundamental Representations shall be true and correct in all but de minimis respects on the Closing Date (except to the extent such representations and warranties by their terms speak as of an earlier date, in which case they shall be true and correct in all but de minimis respects as of such date);

(b) Covenants of Purchaser. Purchaser shall have performed and complied in all material respects with all covenants contained in this Agreement and the Transition Services Agreement to be performed by it prior to the Closing;

(c) Officer's Certificate. Seller shall have received a certificate signed by an authorized executive officer of Purchaser, dated the Closing Date, to the effect that the conditions specified in Sections 7.3(a) and 7.3(b) are satisfied; and

(d) Closing Deliverables. Seller shall have received the deliverables required under Section 8.2 hereof.

ARTICLE VIII CLOSING

8.1 Closing Date.

Unless this Agreement shall have been terminated pursuant to Article X hereof, the closing of the Purchase and the other transactions hereunder (the "Closing") shall take place through the electronic exchange of deliverables and wire transfer of funds at 8:00 a.m. Dublin Time and in such other places as are necessary to effect the transactions to be consummated at the Closing, on the third Business Day immediately following the satisfaction or, to the extent permitted by Law, waiver of all of the conditions in Article VIII (other than those conditions which by their nature are to be satisfied or, to the extent permitted by Law, waived at the Closing but subject to the satisfaction or, to the extent permitted by Law, waiver of such conditions), or at such other time, date and place as shall be fixed by mutual agreement of the Parties; provided, that notwithstanding the satisfaction of the conditions to the obligations of Purchaser and Seller under Article VIII (or, to the extent permitted by Law, the waiver of such conditions by the Parties entitled to waive such conditions). The date on which the Closing occurs is referred to herein as the "Closing Date". The effective time ("Effective Time") of the Closing for tax, operational and all other matters shall be deemed to be 12:01 a.m., local time in each jurisdiction in which the Business is conducted, on the Closing Date.

8.2 Purchaser Obligations.

At the Closing, Purchaser shall, or shall cause one or more of its Subsidiaries to deliver to Seller the Purchase Price *less* the amount of the Redemption Payment, by wire transfer of immediately available funds to an account designated by Seller (provided that Seller shall have delivered to Parent wire instructions no later than three Business Days prior to the Closing Date), (ii) deliver to AIB by wire transfer of immediately available funds to an account designated by AIB, on behalf of Seller, a sum equal to the amount outstanding in respect of AIB Loan (including all principal, accrued interest, fees and/or penalties), as set out in the letter of confirmation to be delivered to the Purchaser pursuant to Section 8.3(a)(vi) (the "Redemption Payment") and (iii) deliver to Seller the following in such form and substance as are reasonably acceptable to Seller:

- (a) an executed copy of an Assignment and Assumption Agreement, substantially in the form of Exhibit E (the "Assignment and Assumption Agreement");
- (b) an executed copy of Transfer;
- (c) an executed copy of the Collateral Warranty Assignment Deed; and
- (d) the other documents described in Section 7.3.

For the purposes of this Section 8.2, Seller hereby irrevocably authorizes and instructs Purchaser to pay (or to procure the payment of) the Redemption Payment to AIB in accordance with Section 8.2 and confirms that the receipt of such funds by AIB shall be sufficient evidence of payment and shall be in full and final discharge of Purchaser's obligation to make such payments.

8.3 Seller Obligations.

(a) At the Closing, Seller shall deliver (and Parent shall cause to be delivered) to Purchaser the following in such form and substance as are reasonably acceptable to Purchaser:

- (i) an executed copy of the Assignment and Assumption Agreement;
- (ii) an executed copy of the Transfer;
- (iii) an executed copy of the Collateral Warranty Assignment Deed;
- (iv) the original Title Leases;
- (v) an executed copy of the Contract for Sale and all documents listed in the documents schedule to the Contract for Sale;
- (vi) a letter of confirmation from AIB confirming (A) all sums (including principal, accrued interest, fees and/or penalties) owing to AIB pursuant to the AIB Loan (B) that on repayment of such sums, AIB will release the AIB Charges and (C) an account and wire instructions into which the Redemption Payment is to be made for the purpose of discharging all such sums;
- (vii) deeds of release in respect of the AIB Charges and the release of the Business and Assets from any Lien or other security created by the Seller or otherwise arising;
- (viii) fully executed CRO C6 Forms in respect of the AIB Charges;
- (ix) the other documents described in Section 7.2;
- (x) delivery of all of the tangible Transferred Assets which are capable of transferring by delivery; and
- (xi) in relation to each Transferred Contract, an assignment or novation agreement in the agreed form duly executed by Seller (or the relevant member of the Seller Group where Seller isn't a party to the relevant Transferred Contract) and, in the case of a novation agreement, by the other party or parties to that contract.

(b) At the Closing, subject to the Transition Services Agreement, Seller will, at its own cost, ensure that the Excluded Assets are removed, from any properties constituting part of the Transferred Assets, as soon as reasonably practicable after Closing with the minimum inconvenience to Purchaser and minimum damage to any of the Transferred Assets. Any Excluded Asset which remains on any property constituting part of the Transferred Assets after Closing will, subject to the Transition Services Agreement, be at the Seller's sole risk.

**ARTICLE IX
INDEMNIFICATION**

9.1 Survival.

(a) Subject to Section 9.1(b), each representation and warranty contained in Article IV and Article V shall survive the Closing and shall terminate on the eighteen (18) month anniversary of the Closing Date, except that (i) the Seller Fundamental Representations and Purchaser Fundamental Representations shall survive the Closing, and shall terminate on the six (6) year anniversary of the Closing Date and (ii) the representations and warranties contained in Section 4.14 shall survive the Closing Date and shall remain in full force until 60 days past the expiration of the applicable statute of limitations for the Taxes in question (taking into account any extensions or waivers thereof). The covenants and agreements contained in this Agreement (i) that are required to be performed in whole prior to the Closing shall survive the Closing and shall terminate on the eighteen (18) month anniversary of the Closing Date and (ii) that require performance after the Closing shall survive until the expiration of the applicable statute of limitations (taking into account any extensions or waivers thereof).

(b) Notwithstanding anything herein to the contrary, the obligations to indemnify and hold harmless a Person pursuant to this Article IX in respect of a breach of representation or warranty, covenant or agreement shall terminate on the applicable survival termination date (as set forth in Section 9.1(a)), unless an Indemnified Party shall have made a claim for indemnification pursuant to Section 9.2 or Section 9.3, subject to the terms and conditions of this Article IX, prior to such survival termination date, as applicable, including by delivering an Indemnification Claim Notice to the Indemnifying Party. Notwithstanding anything herein to the contrary, if an Indemnified Party has made a claim for indemnification pursuant to Section 9.2 or Section 9.3 and delivered an Indemnification Claim Notice to the Indemnifying Party prior to such survival termination date, then such claim (and only such claim), if then unresolved, shall not be extinguished by the passage of the deadlines set forth in Section 9.1(a).

(c) In determining the existence of, and any Losses arising from, any inaccuracy or breach of a representation or warranty herein, the terms “material” or “materially,” any clause or phrase containing “material,” “materially,” “material respects,” “Material Adverse Effect,” “Purchaser Material Adverse Effect” or any similar terms, clauses or phrases in any such representation or warranty shall be disregarded (as if such word or clause, as applicable, were deleted from such representation, warranty or covenant).

9.2 Indemnification by Seller.

Subject to the limitations set forth in this Article IX, from and after the Closing, Seller agrees to indemnify, defend and hold Purchaser, each of its Affiliates and each of their respective Representatives (collectively, the “Purchaser Indemnified Persons”) harmless from and in respect of any and all Losses that they may incur arising out of, relating to or resulting from:

(a) any breach or inaccuracy of any representations or warranties of Seller set forth in Article IV or the certificate delivered pursuant to Section 7.2;

(b) any breach or failure of Seller or its Affiliates to perform any of its covenants or other agreements contained in this Agreement; and/or

(c) any Excluded Asset and/or any Excluded Liability.

9.3 Indemnification by Purchaser.

Subject to the limitations set forth in this Article IX, from and after the Closing, Purchaser agrees to indemnify, defend and hold Seller, its Affiliates and each of their respective Representatives (collectively, the “Seller Group Indemnified Persons”) harmless from and in respect of any and all Losses that they may incur arising out of, relating to or resulting from:

(a) any breach or inaccuracy of any representations or warranties of Purchaser set forth in Article V or the certificate delivered pursuant to Section 7.3(c);

(b) any failure of Purchaser to perform any of its covenants or other agreements contained in this Agreement;

(c) any Transferred Assets and/or any Transferred Liability, in each case of the foregoing, solely to the extent arising out of or relating to the period after the Closing Date (except, in each case of the foregoing, for such portion of any Loss with respect to which Seller would be obligated to indemnify Purchaser Indemnified Persons hereunder); and/or

(d) (i) any Transfer Taxes allocable to Purchaser pursuant to Section 6.8(a) and (ii) any VAT pursuant to Section 6.8(b).

9.4 Limitations on Indemnification.

The Person making a claim for indemnification under this Article IX is referred to herein as the “Indemnified Party” and the Party against whom such claims for indemnification are asserted under this Article IX is referred to herein as the “Indemnifying Party”. Notwithstanding anything herein to the contrary and other than with respect to Fraud, the indemnification obligations of an Indemnifying Party pursuant to this Agreement shall be subject to the following limitations:

(a) De Minimis. No Indemnifying Party shall be liable to an Indemnified Party for, and no Indemnified Party shall be entitled to, any indemnification for Losses pursuant to Section 9.2(a) or Section 9.3(a), as the case may be (other than with respect to breaches of Purchaser Fundamental Representations and Seller Fundamental Representations), unless the amount of any indemnifiable Losses in respect of indemnification pursuant to Section 9.2(a) or Section 9.3(a), as the case may be (other than with respect to breaches of Purchaser Fundamental Representations and Seller Fundamental Representations), would exceed, on a single claim (or a group of claims relating to the same facts or circumstances, event or transaction) \$25,000, and then only to the extent such Losses exceed \$25,000; provided, however, to the extent that the cumulative Losses in excess of such \$25,000 threshold exceed \$250,000, then all of such Losses from the first dollar shall be taken into account in determining whether cumulative Losses exceed the Deductible and will be recoverable to the extent such Losses exceed the Deductible in accordance with this Section 9.4(b).

(b) Deductible. No Indemnifying Party shall be liable to an Indemnified Party for, and no Indemnified Party shall be entitled to, any indemnification for Losses pursuant to Section 9.2(a) or Section 9.3(a), as the case may be (other than with respect to breaches of Purchaser Fundamental Representations, Seller Fundamental Representations and breaches of any representation or warranty set forth in Section 4.14), unless the aggregate of all indemnifiable Losses in respect of indemnification pursuant to Section 9.2(a) or Section 9.3(a), as the case may be (other than with respect to breaches of Purchaser Fundamental Representations, Seller Fundamental Representations and breaches of any representation or warranty set forth in Section 4.14), would exceed on a cumulative basis \$650,000 (the “Deductible”), and then only to the extent such Losses exceed the Deductible.

(c) Maximum Amount. The maximum amount of indemnifiable Losses that an Indemnifying Party shall be liable for, or that may be recovered by an Indemnified Party, in the aggregate pursuant to Section 9.2(a) or Section 9.3(a), as the case may be (other than with respect to breaches of Purchaser Fundamental Representations, Seller Fundamental Representations and breaches of any representation or warranty set forth in Section 4.14), shall be \$10,000,000. The maximum amount of indemnifiable Losses that an Indemnifying Party shall be liable for, or that may be recovered by an Indemnified Party, in the aggregate pursuant to Section 9.2(a) (with respect to breaches of the Seller Fundamental Representations), Section 9.3(a) (with respect to breaches of Purchaser Fundamental Representations), Section 9.2(b) and Section 9.3(b) shall be the Purchase Price. There shall be no cap on the amount of indemnifiable Losses that an Indemnifying Party shall be liable for, or that may be recovered by an Indemnified Party with respect to, Section 9.2(c), and/or Section 9.3(c).

(d) Insurance and Other Payments. Payments by an Indemnifying Party pursuant to Section 9.2 or Section 9.3 in respect of any Loss shall be limited to the amount of any Liability or damage that remains after deducting therefrom any insurance proceeds and any indemnity, contribution or other similar payment actually received by the Indemnified Party (or its Affiliates) from any third parties (other than the Indemnifying Party) in respect of any such claim, net of any costs of recovery, and increases in premiums.

(e) No Duplication. Losses shall be determined without duplication of any other Loss for which an indemnification claim has been made or could be made under any other representation, warranty, covenant or agreement. The Indemnified Parties shall not be entitled to recover more than once for the same Loss.

(f) No Setoff Rights. Neither Party shall have any right of setoff of any amounts due and payable, or any amounts arising, under this Agreement against any other amounts due and payable, or liabilities arising, under the Transition Services Agreement. The payment obligations under this Agreement, and the Transition Services Agreement remain independent obligations of each Party, irrespective of any amounts owed to any other Party under this Agreement or the or Transition Services Agreement, as the case may be.

(g) WAIVER. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND EXCEPT AS A RESULT OF FRAUD, NO PARTY SHALL

BE LIABLE TO ANY OTHER PARTY, OR THEIR AFFILIATES, FOR ANY LOSSES THAT ARE IN THE NATURE OF SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES, EXCEPT TO THE EXTENT THAT SUCH LOSSES ARE REQUIRED TO BE PAID BY AN INDEMNIFIED PARTY IN CONNECTION WITH A THIRD PARTY CLAIM, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED UPON BREACH OF CONTRACT, TORT, BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER THEORY OF RECOVERY.

(h) Conflicting Claims. Notwithstanding anything herein to the contrary, (i) none of the Transferred Liabilities (or the transfer thereof) shall (x) diminish any Purchaser Indemnified Person's recovery for Losses under this Agreement to the extent such Losses relate to any breach by the Seller Group of any of its representations, warranties or covenants in this Agreement, any of the Transaction Documents or any of the certificates delivered hereunder or thereunder, in each case by any member of the Seller Group or (y) prevent the inclusion of any portion of any Transferred Liability and (ii) none of the Excluded Liabilities (or the retention thereof) shall diminish any Seller Group Indemnified Person's recovery for Losses under this Agreement to the extent such Losses relate to any breach by Purchaser of any representations, warranties or covenants in this Agreement, any of the Transaction Documents or any of the certificates delivered hereunder or thereunder, in each case by Purchaser.

9.5 Indemnification Procedures.

(a) Claim Procedure. In order for any Indemnified Party to be entitled to make a claim for indemnification under this Article IX, such Indemnified Party shall deliver a written notice (an "Indemnification Claim Notice") to the Indemnifying Party, as promptly as reasonably practicable after it acquires knowledge of the fact, event or circumstance giving rise to a claim for Losses pursuant to this Article IX. Each Indemnification Claim Notice shall specify in reasonable detail the nature of, the facts, circumstances and the amount or a good faith estimate (only to the extent ascertainable) of the potential Losses against which such Indemnified Party seeks indemnification for, such claim asserted, and the provisions of this Agreement upon which such claim for indemnification is made; provided, however, that any failure by such Indemnified Party to give such prompt Indemnification Claim Notice shall not relieve the Indemnifying Party of its indemnification obligations, except and only to the extent that the Indemnifying Party is actually and materially prejudiced thereby. After delivery of an Indemnification Claim Notice to the Indemnifying Party, (i) the Indemnified Party which has provided such Indemnification Claim Notice shall, upon written request from the Indemnifying Party, supply and make available to the Indemnifying Party and its Representatives (at the Indemnifying Party's cost and expense) all relevant information in its or its Affiliates' possession relating to the claim reasonably requested by the Indemnifying Party (except to the extent that such action would result in a loss of attorney-client privilege; provided, that such Indemnified Party shall use its commercially reasonable efforts to provide such information in such format to the Indemnifying Party, or on an outside counsel only basis or in such other manner which would not result in the loss of such attorney-client privilege) and (ii) the Indemnified Party shall, and shall cause its Representatives, to (A) be reasonably available to the Indemnifying Party and its Representatives (at the Indemnifying Party's cost and expense) during normal business

hours to discuss such claim, (B) render to the Indemnifying Party and its Representatives such assistance as may reasonably be requested, (C) provide reasonable access to such properties, facilities, books, records, accountant work papers and other documents or information in their possession or that may be reasonably obtained as the Indemnifying Party and/or its Representatives may reasonably require (at the Indemnifying Party's cost and expense) (provided, that the accountants of the Indemnified Party shall not be obligated to make any working papers available to the Indemnifying Party or its Representatives unless and until such Party or such Representative, as applicable, has signed a customary confidentiality and hold harmless agreement relating to such access to working papers in form and substance reasonably acceptable to such accountants), and (D) otherwise cooperate with the Indemnifying Party and its Representatives in good faith (at the Indemnifying Party's cost and expense). Without limiting the foregoing, such cooperation shall include the retention and (upon the Indemnifying Party's request) the provision to the Indemnifying Party or its Representatives of books, records and other documents and information which are actually and reasonably relevant to such claim.

(b) Direct Claims. Any claim by an Indemnified Party on account of a Loss which does not result from a Third-Party Claim (a "Direct Claim") shall be asserted by the Indemnified Party by delivering an Indemnification Claim Notice with respect to such Direct Claim to the Indemnifying Party promptly; provided, however, that any failure by such Indemnified Party to give such prompt Indemnification Claim Notice shall not relieve the Indemnifying Party of its indemnification obligations, except and only to the extent that the Indemnifying Party is actually and materially prejudiced thereby. The Indemnified Party shall allow the Indemnifying Party and its Representatives to investigate the matter or circumstance alleged to give rise to the Direct Claim, and whether and to what extent any amount is payable in respect of the Direct Claim and the Indemnified Party as provided in Section 9.5(a). The Indemnifying Party may, within thirty (30) days after receipt of an Indemnification Claim Notice with respect to such Direct Claim, deliver to the Indemnified Party a written response disputing such claim, which response must state in reasonable detail the reasons why the Indemnifying Party disputes such claim, together with reasonable supporting detail. If the Indemnifying Party fails to deliver a written response disputing such claim within such thirty (30) day period, the Indemnifying Party will be deemed to have waived its right to dispute such claim and such claim shall have been deemed to have been agreed to by the Indemnifying Party.

(c) Deemed withdrawal of Direct Claims. Save to the extent to which such Direct Claim has previously been satisfied, settled or withdrawn, any Direct Claim by an Indemnified Party shall not be enforceable against the Indemnifying Party and shall be deemed to have been withdrawn unless (except as agreed by the Parties otherwise) Proceedings in respect of such claim are commenced, subject to Section 9.5(d), by the Indemnified Party within nine months of service of notice of any dispute by the Indemnifying Party pursuant to Section 9.5(b).

(d) Contingent Liabilities. Where any Direct Claim by an Indemnified Party relates to a Loss which, at the time that such claim is notified to the Indemnifying Party is a contingent liability, the Indemnifying Party shall not be under any obligation to make any payment to an Indemnified Party in respect thereof and unless and until such time as the contingent liability ceases to be contingent and becomes actual

and is due and payable. If an Indemnified Party has issued a notice in respect of such Direct Claim in accordance with Section 9.5(b) before the expiry of the relevant time periods for making such a claim against relevant the Indemnifying Party set out in Section 9.1(a), the 9 month time period in Section 9.5(c) shall be deemed to commence upon the date which the liability ceases to be contingent and becomes an actual liability and is due and payable.

(e) Third-Party Claims.

(i) If any Indemnified Party receives notice of the assertion or commencement of any action made or brought by any Person who is not a party to this Agreement or an Affiliate of a party to this Agreement (a “Third-Party Claim”) against such Indemnified Party with respect to which such Indemnifying Party may be obligated to provide indemnification under this Agreement, such Indemnified Party shall deliver an Indemnification Claim Notice with respect to such Third-Party Claim to the Indemnifying Party promptly; provided, however, the failure to give such prompt Indemnification Claim Notice shall not relieve the Indemnifying Party of its indemnification obligations, except and only to the extent that the Indemnifying Party is actually and materially prejudiced thereby. Such Indemnification Claim Notice by the Indemnified Party shall describe the Third-Party Claim in reasonable detail, and where reasonably practicable, shall include copies of all letters, claims, complaints, filings, documents and correspondence received by the Indemnified Party or its Representatives with respect thereto.

(ii) The Indemnifying Party shall have the right, but not the obligation, to investigate, participate in, or by giving written notice to the Indemnified Party within thirty (30) days of receipt of the Indemnification Claim Notice relating to such Third-Party Claim to assume and control the defense of, or settle (subject to Section 9.5(e)(v)), any Third-Party Claim at the Indemnifying Party’s expense and by the Indemnifying Party’s own counsel, and the Indemnified Party shall cooperate in good faith in such defense.

(iii) In the event that the Indemnifying Party timely notifies the Indemnified Party it desires (and is permitted pursuant to Section 9.5) to assume and control the defense of any Third-Party Claim pursuant to Section 9.5(e)(ii), it shall diligently prosecute such Third-Party Claim and it shall have the right to take such action as it deems necessary to avoid, dispute, defend, appeal or make counterclaims pertaining to any such Third-Party Claim in the name and on behalf of the Indemnified Party. The Indemnified Party shall have the right, at its own cost and expense, to participate in the defense of any Third-Party Claim that the other Party has assumed the defense of with counsel selected by it subject to the Indemnifying Party’s right to control the defense thereof; provided, that if there exists a conflict of interest between the Indemnifying Party and such Indemnified Party as has been determined by the Indemnified Party’s outside legal counsel or if there are one or more different defenses to such Third-Party Claim, then the Indemnified Party shall have the right to claim the reasonable and documented costs and expenses of one (1) counsel and one (1) local counsel in each applicable jurisdiction as indemnifiable Losses to the extent the Indemnified Party is entitled to be indemnified for such Third-Party Claim.

(iv) If the Indemnifying Party elects not to compromise or defend such Third-Party Claim or is not permitted to defend such Third-Party Claim, fails to promptly notify the Indemnified Party in writing of its election to defend as provided in this Agreement, or fails to diligently defend the Third-Party Claim, the Indemnified Party may, subject to the provisions of this Article IX, pay, compromise or defend such Third-Party Claim and seek indemnification for any and all Losses based upon, arising from or relating to such Third-Party Claim. Each of the Indemnified Party and the Indemnifying Party shall keep the other and the other's Representatives reasonably informed concerning the status of any such Third-Party Claim and any related proceedings and all stages thereof. Each of the Parties and the Indemnifying Party and the Indemnified Party shall cooperate in good faith with each other in all reasonable respects in connection with the defense of any Third-Party Claim, including making available (subject to the confidentiality provisions of this Agreement) and retaining records relevant or relating to such Third-Party Claim and furnishing, without expense (other than reimbursement of actual out-of-pocket expenses) to the defending party, management employees of the non-defending party as may be reasonably necessary for the preparation of the defense for, and the defense of, such Third-Party Claim.

(v) Notwithstanding any other provision of this Agreement, the Indemnifying Party shall not compromise or otherwise enter into any judgment or settlement of any Third-Party Claim without the prior written consent of the Indemnified Party, other than a compromise, judgment or settlement that (A) is on exclusively monetary terms with, subject to the limitations in Section 9.4, such monetary amounts paid by the Indemnifying Party concurrently with the effectiveness of the compromise, judgement or settlement, (B) does not involve any finding or admission of violation of Law or admission of wrongdoing by the Indemnified Party and (C) provides in customary form, an unconditional release of, or dismissal with prejudice of, all claims against any Indemnified Party potentially affected by such Third-Party Claim. If the Indemnified Party has assumed the defense pursuant to Section 9.5(e), it shall not agree to any settlement without the written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

(vi) Notwithstanding the foregoing, if a Third-Party Claim (A) seeks relief other than the payment of monetary damages or could result in the imposition of an Order that would restrict in any respect any present or future activity or conduct of Purchaser or any of its controlled Affiliates, (B) seeks a finding or admission of a violation of Law (including any Third-Party Claim seeking to impose criminal fines, penalties or sanctions) or of any Order or of a violation of the rights of any Person by Purchaser or any of its controlled Affiliates, or (C) is in connection with a Transferred Contract, then, in each such case, Purchaser shall be entitled to solely direct the defense of any such Third-Party Claim.

9.6 Mitigation.

Each Indemnified Party shall take commercially reasonable steps to mitigate all Losses promptly after its senior executives have actually become aware of any event which gives rise to any Losses that are indemnifiable hereunder.

9.7 Treatment of Indemnification Payments.

The Parties agree that any indemnification payments made pursuant to this Agreement shall be treated for Tax purposes as an adjustment to the Purchase Price, unless otherwise required by applicable Law.

ARTICLE X TERMINATION

10.1 Termination Events.

Without prejudice to other remedies which may be available to the Parties by Law or this Agreement, this Agreement may be terminated and the transactions contemplated herein may be abandoned:

(a) by mutual written consent of the Parties;

(b) after October 14, 2021 (the "Outside Date"), by any Party by notice to the other Party if the Closing shall not have been consummated on or prior to 5:00 p.m. Central Time on the Outside Date; provided, however, that the right to terminate this Agreement under this Section 10.1(b) shall not be available to any Party whose failure or whose Affiliate's failure to perform any of its representations, warranties, covenants or other obligations under this Agreement has been the primary cause of, or otherwise primarily resulted in, the failure of the Closing to occur on or prior to such date;

(c) by any Party, if a final, non-appealable Order enjoining or otherwise prohibiting consummation of the Purchase has been issued by any Governmental Authority (unless such order, decree or ruling has been withdrawn, reversed or otherwise made inapplicable) or any Law has been enacted that would make the Purchase illegal;

(d) by Seller if (i) Seller is not in material breach of any of its representations, warranties, covenants or other obligations hereunder that renders or would render the conditions set forth in Sections 7.2(a) or 7.2(b) incapable of being satisfied and (ii) Purchaser is in material breach of any of its representations, warranties, covenants or other obligations hereunder that renders or would render the conditions set forth in Sections 7.3(a) or 7.3(b) incapable of being satisfied, and such breach is either (A) not capable of being cured prior to the Outside Date or (B) if curable, is not cured within the earlier of (x) thirty (30) days after the giving of written notice by Seller to Purchaser and (y) three (3) Business Days prior to the Outside Date; or

(e) by Purchaser if (i) Purchaser is not in material breach of any of its representations, warranties, covenants or other obligations hereunder that renders or would render the conditions set forth in Sections 7.3(a) or 7.3(b) incapable of being satisfied and (ii) Seller is in material breach of any of its representations, warranties, covenants or other obligations hereunder that renders or would render the conditions set forth in Sections 7.2(a) or 7.2(b) incapable of being satisfied, and such breach is either (A) not capable of being cured prior to the Outside Date or (B) if curable, is not cured

within the earlier of (x) thirty (30) days after the giving of written notice by Purchaser to Seller and (y) three (3) Business Days prior to the Outside Date.

10.2 Effect of Termination.

In the event of any termination of this Agreement as provided in this Article X, this Agreement shall forthwith become wholly void and of no further force and effect, all further obligations of the Parties under this Agreement shall terminate and there shall be no liability on the part of any Party (or any Affiliate or Representative of such Party) to any other Party (or such other Persons), except that the provisions of Sections 6.4, 10.2 and Article XI of this Agreement shall remain in full force and effect and the Parties shall remain bound by and continue to be subject to the provisions thereof. Notwithstanding the foregoing, the provisions of this Section 10.2 shall not relieve either Party of any liability for Fraud or for willful misconduct or intentional breach of this Agreement.

**ARTICLE XI
MISCELLANEOUS**

11.1 Notices.

All notices and other communications under this Agreement shall be in writing and shall be deemed given (a) when delivered personally by hand (with written confirmation of receipt, by other than automatic means, whether electronic or otherwise), (b) when sent by e-mail (with written confirmation of transmission) or (c) one (1) Business Day following the day sent by an internationally recognized overnight courier (with written confirmation of receipt), in each case, at the following addresses (or to such other address as a Party may have specified by notice given to the other Party pursuant to this provision):

- (a) If to Seller: EirGen Pharma Limited
Westside Business Park
Old Kilmeaden Road,
Co. Waterford
Ireland
- Attention: Damien Burke, CEO
Email: Damien.burke@eirgen.com

with a copy (which shall not constitute notice) to:

OPKO Health, Inc.
4400 Biscayne Blvd.
Miami, FL 33137

Attention: Legal Department
Email: CGreen@opko.com

and

McCann FitzGerald
Riverside One
Sir John Rogerson's Quay

Dublin 2
Ireland

Attention: Alan Fuller
Email: alan.fuller@mccannfitzgerald.com

(b) If to Parent: OPKO Health, Inc.
4400 Biscayne Blvd.
Miami, FL 33137

Attention: Legal Department
Email: CGreen@opko.com

with a copy (which shall not constitute notice) to:

McCann FitzGerald
Riverside One
Sir John Rogerson's Quay
Dublin 2
Ireland

Attention: Alan Fuller
Email: alan.fuller@mccannfitzgerald.com

(c) If to Purchaser: Horizon Therapeutics Ireland DAC
Connaught House, 1st Fl
1 Burlington Road
Dublin 4, D04 C5Y6
Ireland

Attention: General Counsel
Email: legal@horizontherapeutics.com

with a copy (which shall not constitute notice) to:

Cooley LLP
4401 Eastgate Mall
San Diego, CA 92121
United States of America

Attention: Barbara L. Borden
Rowook Park
Email: bordenbl@cooley.com
rpark@cooley.com

and

Matheson
70 Sir John Rogerson's Quay
Dublin 2

Attention: David Fitzgibbon
John Coary
Email: david.fitzgibbon@matheson.com
john.coary@matheson.com

11.2 Bulk Transfers.

The Parties waive, to the fullest extent permitted by Law, compliance with the provisions of all applicable Laws relating to bulk transfers of any jurisdiction in connection with the transfer of the Transferred Assets.

11.3 Severability.

If any provision of this Agreement shall be declared by any court of competent jurisdiction to be illegal, void or unenforceable, all other provisions of this Agreement and the application of such provision to other persons or circumstances other than those which it is determined to be illegal, void or unenforceable, shall not be impaired or otherwise affected and shall remain in full force and effect to the fullest extent permitted by applicable Law, and Seller and Purchaser shall negotiate in good faith to replace such illegal, void or unenforceable provision with a provision that corresponds as closely as possible to the intentions of the Parties as expressed by such illegal, void or unenforceable provision.

11.4 Further Assurances; Further Cooperation.

Subject to the terms and conditions hereof, each of the Parties agrees to use commercially reasonable efforts to execute and deliver, or cause to be executed and delivered, all documents and to take, or cause to be taken, all actions that may be reasonably necessary or appropriate, in the reasonable opinion of counsel for Seller and Purchaser, to effectuate the provisions of this Agreement (for the avoidance of doubt, including any and all steps required to procure the release of the AIB Charges), provided, that all such actions are in accordance with applicable Law. From time to time, Seller or its Subsidiaries (as appropriate) will execute and deliver such further instruments of conveyance, transfer and assignment and take such other action, at Purchaser's sole expense, as Purchaser may reasonably require to more effectively convey and transfer to Purchaser any of the Transferred Assets, and Purchaser will execute and deliver such further instruments and take such other action, at Seller's sole expense, as Seller or its Subsidiaries may reasonably require to more effectively assume the Transferred Liabilities.

11.5 Counterparts.

This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument. Copies of executed counterparts transmitted by electronic signature (including by means of e-mail in .pdf format) shall be considered original executed counterparts for purposes of this Section 11.5.

11.6 Expenses.

Except as otherwise expressly provided herein, whether or not the Closing occurs, Seller and Purchaser shall each pay their respective expenses incurred in connection with the negotiation and execution of this Agreement and the other Transaction Documents and the consummation of the transactions contemplated hereby and thereby.

11.7 Assignment; Successors and Assigns.

This Agreement shall be binding upon and inure to the benefit of the Parties to this Agreement and their respective permitted successors and assigns; provided, however, that no Party to this Agreement may directly or indirectly assign any or all of its rights or delegate any or all of its obligations under this Agreement without the express prior written consent of the other Parties to this Agreement, except that, (i) either Party may: (A) collaterally assign its rights hereunder to any lender or debt financing source of such Party or any of its Affiliates and (B) after the Closing, assign all or part of its rights or obligations hereunder to any Person in connection with an internal restructuring, joint venture, sale or divestiture of all or any part of the equity interests or the assets of such Party or any of its Affiliates and (ii) Purchaser may assign all or part of its rights or obligations hereunder to one or more of its Affiliates, without the consent of the other Party (in the case of clause (i)) or Seller (in the case of clause (ii)). No assignment of any obligations hereunder shall relieve the Parties of any such obligations. Subject to the preceding sentence, this Agreement will be binding upon, inure to the benefit of, and be enforceable by the Parties and their respective successors and permitted assigns.

11.8 Amendment; Waiver.

This Agreement may be amended, supplemented or otherwise modified only by a written instrument executed by all of the Parties. No waiver by any Party of any of the provisions hereof shall be effective unless explicitly set forth in writing and executed by the Party so waiving. Except as provided in the preceding sentence, no action taken pursuant to this Agreement, including any investigation by or on behalf of any Party, or a failure or delay by any Party in exercising any power, right or privilege under this Agreement shall be deemed to constitute a waiver by the Party taking such action of compliance with any representations, warranties, covenants, or agreements contained herein, and in any documents delivered or to be delivered pursuant to this Agreement and in connection with the Closing hereunder. The waiver by any Party of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

11.9 Remedies.

(a) The Parties acknowledge and agree that irreparable damage would occur and that the Parties may not have any adequate remedy at Law in the event that any provision of this Agreement were not performed in accordance with its specific terms or were otherwise breached, and that money damages or other legal remedies would not be an adequate remedy for any such failure to perform or any such breach. Accordingly, the Parties hereto acknowledge and hereby agree that in the event of any breach or threatened breach by Seller or Purchaser of any of their respective covenants or obligations set forth in this Agreement, each of Purchaser and Seller, respectively, shall be entitled to an injunction or injunctions to prevent or restrain breaches or threatened breaches of this Agreement by such other Party (as applicable), and to specifically enforce the terms and provisions of this Agreement to prevent breaches or threatened breaches of, or to enforce compliance with, the covenants and obligations of the other (as applicable) under this Agreement, without proof of actual damages or inadequacy of legal

remedy and without bond or other security being required. The pursuit of specific enforcement or other equitable remedies by any Party will not be deemed an election of remedies or waiver of the right to pursue any other right or remedy (whether at Law or in equity) to which such Party may be entitled at any time.

(b) Any and all remedies herein expressly conferred upon a Party will be deemed cumulative with and not exclusive of any other remedy conferred hereby, or by Law or equity upon such Party, and the exercise by a Party of any one remedy will not preclude the exercise at any time of any other remedy.

(c) Each of Seller and Purchaser hereby agrees not to raise any objections to the availability of the equitable remedy of specific performance to prevent or restrain breaches or threatened breaches of this Agreement by Seller or Purchaser, as applicable, and to specifically enforce the terms and provisions of this Agreement to prevent breaches or threatened breaches of, or to enforce compliance with, the covenants and obligations of Seller or Purchaser, as applicable, under this Agreement. The Parties hereto further acknowledge and agree that (i) by seeking the remedies provided for in this Section 11.9, a Party shall not in any respect waive its right to seek at any time any other form or amount of relief that may be available to a Party under this Agreement (including monetary damages) and (ii) nothing set forth in this Section 11.9 shall require any Party to institute any proceeding for (or limit any Party's right to institute any proceeding for) specific performance under this Section 11.9 prior or as a condition to exercising any termination right under Article X (and pursuing damages after such termination (subject to the terms of this Agreement)), nor shall the commencement of any Proceeding pursuant to this Section 11.9 or anything set forth in this Section 11.9 restrict or limit any Party's right to terminate this Agreement in accordance with the terms of Article X or pursue any other remedies under this Agreement or otherwise that may be available then or thereafter.

11.10 Third Parties.

This Agreement does not create any rights, claims or benefits inuring to any Person that is not a Party nor create or establish any third-party beneficiary hereto (including with respect to any Business Employee); provided, however, that, notwithstanding the foregoing, Purchaser Indemnified Persons and Seller Group Indemnified Persons are intended third-party beneficiaries of, and may enforce, Article IX.

11.11 Governing Law.

Other than Sections 2.1, 8.3 and 11.16, this Agreement, and all claims or causes of action (whether in contract, tort or otherwise) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement) shall be governed by and construed in accordance with the law of Ireland, without giving effect to any laws, rules or provisions that would cause the application of the laws of any jurisdiction other than Ireland. Sections 2.1, 8.3 and 11.16, and all claims or causes of action (whether in contract, tort or otherwise) that may be based upon, arise out of or relate to Sections 2.1, 8.3 and 11.16 or the negotiation, execution or performance of Sections 2.1, 8.3 and 11.16 (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection

with Sections 2.1, 8.3 and 11.16) shall be governed by and construed in accordance with the law of the State of Delaware.

11.12 Dispute Resolution.

(a) As between Purchaser and Parent, each of Purchaser and Parent hereby irrevocably and unconditionally (a) submits, for itself and its property, to the exclusive jurisdiction of the Delaware Court of Chancery (or, only if the Delaware Court of Chancery declines to accept jurisdiction over a particular matter, any Federal court of the United States of America sitting in the State of Delaware), and any appellate court from any thereof, in any Proceeding arising out of or relating to Sections 2.1, 8.3 or 11.16 or the negotiation, execution or performance of Sections 2.1, 8.3 and 11.16 (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with Sections 2.1, 8.3 or 11.16), or for recognition or enforcement of any judgment, and agrees that all claims in respect of any such Proceeding shall be heard and determined in such Delaware Court of Chancery (or, only if the Delaware Court of Chancery declines to accept jurisdiction over a particular matter, any Federal court of the United States of America sitting in the State of Delaware), (b) waives, to the fullest extent it may legally and effectively do so, any objection which it may now or hereafter have to the laying of venue of any Proceeding arising out of or relating to Sections 2.1, 8.3 or 11.16 or the negotiation, execution or performance of Sections 2.1, 8.3 or 11.16 (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with Sections 2.1, 8.3 or 11.16) in the Delaware Court of Chancery, any Federal court of the United States of America sitting in the State of Delaware, or in any Delaware State court, (c) waives, to the fullest extent permitted by Law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court, and (d) agrees that a final judgment in any such Proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Law. Each of Purchaser and Parent hereto agrees that service of process, summons, notice or document by registered mail addressed to it at the applicable address set forth in Section 11.1 shall be effective service of process for any Proceeding brought in any such court.

(b) Except as set forth in Section 11.12(a), any and all such disputes that cannot be resolved by the Parties shall be settled solely and exclusively by arbitration in New York, New York pursuant to the commercial rules then in effect of the International Chamber of Commerce, and the merits of the dispute shall be resolved in accordance with the laws of Ireland. The arbitration shall be conducted by an arbitration panel consisting of three (3) arbitrators, each of whom shall be knowledgeable in the subject matter hereof. Each of Purchaser, on one hand, and Parent and Seller, on the other hand, shall select one of the arbitrators, and the two selected arbitrators shall select the third arbitrator. The arbitrators will provide a written explanation to the Parties of any arbitration award. Any decision rendered by the arbitration panel shall be binding, final and conclusive upon the Parties, and a judgment thereon may be entered in, and enforced by, any court having jurisdiction over the Party against which an award is entered or the location of such Party's assets, and the Parties hereby irrevocably waive any objection to the jurisdiction of such courts based on any ground, including without limitation, improper venue or forum non-conveniens. Except where clearly prevented by the subject matter of the dispute, all Parties shall continue performing their respective obligations

under this Agreement while this dispute is being resolved. Parties and the arbitration panel shall be bound to maintain the confidentiality of this Agreement, the dispute and any award, except to the extent necessary to enforce any such award. The prevailing Party, if a Party is so designated in the arbitration award, shall be entitled to recover from the other Party its costs and fees, including attorneys' fees, associated with such arbitration.

(c) THE PARTIES HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVE ANY RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTION DOCUMENTS OR ANY TRANSACTION CONTEMPLATED HEREBY OR THEREBY OR THE ACTIONS OF THE PARTIES IN THE NEGOTIATION, EXECUTION, PERFORMANCE AND ENFORCEMENT OF THIS AGREEMENT OR THE TRANSACTION DOCUMENTS, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE TRIAL BY JURY AND THAT ANY ACTION OR PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT, THE TRANSACTION DOCUMENTS OR ANY TRANSACTION CONTEMPLATED HEREBY OR THEREBY SHALL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

11.13 Disclosure Schedules.

The Disclosure Schedules is hereby incorporated and made a part hereof and is an integral part of this Agreement. Disclosures included in the Disclosure Schedules shall be considered to be made for purposes of all other sections to the Disclosure Schedules to the extent that the relevance of any disclosure to any such other section of the Disclosure Schedules is reasonably apparent. Inclusion of any matter or item in the Disclosure Schedules does not imply that such matter or item would, under the provisions of this Agreement, have to be included in the Disclosure Schedules or that such matter or item is otherwise material. Reference to any Contract set forth in the Disclosure Schedules shall be deemed to include all amendments, purchase orders and schedules thereto from time to time through the date of this Agreement. Nothing contained in the Disclosure Schedules should be construed as an admission of liability or responsibility of any Party to any third party in connection with any pending or threatened Proceeding or otherwise. Any capitalized terms used in the Disclosure Schedules but not otherwise defined therein shall be defined as set forth in this Agreement.

11.14 Entire Agreement.

This Agreement, the other Transaction Documents, the Disclosure Schedules and the Exhibits hereto and any other agreements between Purchaser and Seller entered into on the date hereof set forth the entire understanding of the Parties with respect to the subject matter hereof and there are no agreements, understandings, representations or warranties between the Parties or their respective Subsidiaries other than those set forth or referred to herein or therein. In the event of any inconsistency between the provisions of this Agreement and any other Transaction Document, the provisions of this Agreement shall prevail.

11.15 No Joint Venture.

Nothing in this Agreement creates a joint venture or partnership between the Parties. This Agreement does not authorize any Party (i) to bind or commit, or to act as an agent, employee or legal Representative of, another Party, except as may be specifically set forth in other provisions of this Agreement or (ii) to have the power to control the activities and operations of another Party. The Parties are independent contractors with respect to each other under this Agreement. Each Party agrees not to hold itself out as having any authority or relationship contrary to this Section 11.15.

11.16 Parent Guarantee.

(a) Parent irrevocably guarantees each and every covenant and obligation of Seller and the full and timely performance of Seller's obligations under the provisions of this Agreement. This is a guaranty of performance, and not of collection, and Parent acknowledges and agrees that this guaranty is full and unconditional, and no release or extinguishments of Seller's liabilities, whether by decree in any bankruptcy proceeding or otherwise, will affect the continuing validity and enforceability of this guaranty. Parent hereby waives, for the benefit of each Purchaser Indemnified Person, (i) any right to require any Purchaser Indemnified Person as a condition of performance of Parent to proceed against Seller or pursue any other remedies whatsoever and (ii) to the fullest extent permitted by applicable Law, any defenses or benefits that may be derived from or afforded by law that limit the liability of or exonerate guarantors or sureties, except to the extent that any such defense is available to Seller. Parent understands that Purchaser is relying on this guaranty in entering into this Agreement.

(b) Parent hereby represents and warrants to Purchaser that: (i) Parent is duly organized, validly existing and in good standing under the laws of the State of Delaware, (ii) Parent has full power and authority to execute and deliver this Agreement and to perform its obligations under this guaranty and Sections 2.1 and 8.3, (iii) the execution and delivery by Parent of this Agreement and the performance of its obligations under this guaranty and Sections 2.1 and 8.3 have been duly authorized by all requisite corporate action on the part of Parent and (iv) this Agreement has been duly executed and delivered by Parent, and this guaranty and Sections 2.1 and 8.3 constitutes legal, valid and binding obligations of Parent, enforceable against Parent in accordance with its terms, except as enforceability may be affected by bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar Laws relating to or affecting creditors' rights generally, general equitable principles (whether considered in a proceeding in equity or at law) and the implied covenant of good faith and fair dealing.

11.17 Section Headings; Table of Contents.

The Section headings contained in this Agreement and the Table of Contents to this Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Agreement.

IN WITNESS WHEREOF, the Parties have caused this Asset Purchase Agreement to be duly executed as of the date first above written.

Signed for and on behalf of EIRGEN PHARMA LIMITED:	/s/ Damien Burke
	Damien Burke Chief Executive Officer

Signed for and on behalf of HORIZON THERAPEUTICS IRELAND DAC:	/s/Alan Mac Neice
	Alan Mac Neice Director

Signed for and on behalf of OPKO Health, Inc. (solely for the purposes of <u>Sections 2.1, 8.3 and 11.16</u>):	/s/Steven Rubin
	Steven Rubin Executive Vice President, Administration

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Execution Version

LICENSE AGREEMENT
BY AND AMONG
EIRGEN PHARMA LIMITED
AND
NICOYA MACAU LIMITED

June 17, 2021

Table of Contents

	Page
1 Definitions; Interpretation	1
1.1 Defined Terms.	1
1.2 Interpretation.	11
2 Grant of Rights	12
2.1 OPKO Patents, OPKO Technology, Other Licensee Patents and Other Licensee Technology.	12
2.2 Licensee Patents and Licensee Technology.	13
2.3 Retained Rights.	14
2.4 Subcontracting.	14
2.5 Ex-Territory and Ex-Field Activities.	14
2.6 Licensee Right of First Refusal for [***] Products.	15
3 Term	16
3.1 Term.	16
3.2 Expiration.	16
4 Fees and Payments	16
4.1 Upfront Payment.	16
4.2 Milestone Payments.	16
4.3 Royalty Payments.	17
4.4 Royalty Term.	18
4.5 Royalty Reductions and Credits.	18
4.6 Late Payments.	19
4.7 Reports, Timing and Method of Payments, and Foreign Exchange.	19
4.8 Taxes.	20
4.9 Currency Exchange.	20
4.1 Adjustments.	20
5 Clinical Data	21
5.1 Data Sharing.	21
6 Regulatory Matters	21
6.1 Regulatory Filings and Regulatory Approvals.	21
6.2 Right of Reference to Regulatory Filings; Third Party Clinical Data.	22
6.3 Cooperation.	23
6.4 Threatened Regulatory Action.	23
6.5 Recalls.	23
7 Commercialization	24
7.1 Licensee Efforts.	24
7.2 Promotional Activities.	24

8	Governance	25
8.1	Joint Steering Committee.	25
8.2	JSC Membership.	26
8.3	JSC Meetings.	26
8.4	Alliance Managers.	26
9	Manufacturing, Distribution and Supply	27
9.1	Manufacture and Supply by OPKO.	27
9.2	Manufacturing Specific Provisions.	27
10	Safety and Surveillance	28
10.1	Reporting.	28
10.2	Adverse Events.	28
10.3	Medical Inquiries.	29
10.4	Recall, Withdrawal, or Market Notification of Product.	29
11	Audit Rights	29
11.1	Audit Rights.	29
12	Intellectual Property	30
12.1	Ownership of Intellectual Property.	30
12.2	Patent Prosecution.	30
12.3	Notification of Patent Litigation.	31
12.4	Patent Infringement.	32
12.5	Title to Trademarks.	33
12.6	Trademark License of OPKO Trademark.	33
12.7	Maintenance of OPKO Trademarks.	33
12.8	Notification of Trademark Litigation.	34
12.9	Trademark Infringement.	34
12.1	Information and Settlements.	35
12.11	Employees.	35
12.12	Third Party Licenses.	35
13	Confidentiality	36
13.1	Disclosure of OPKO Technology.	36
13.2	Confidential Information.	36
13.3	Public Announcements.	36
14	Restrictive Covenants	37
14.1	Non-solicitation.	37
14.2	Non-competition.	37
15	Termination; Rights And Duties Upon Termination	37
15.1	Early Termination.	37
15.2	Continuing Obligations.	38

15.3	Remedies.	39
15.4	Effects of Termination.	39
16	Representations, Warranties, Covenants, and Indemnification	41
16.1	Mutual Representations and Warranties.	41
16.2	Representations and Warranties of OPKO.	41
16.3	OPKO Covenant.	43
16.4	Compliance with Law and Ethical Business Practices.	43
16.5	Indemnification by OPKO.	44
16.6	Indemnification by Licensee.	44
16.7	Limitations on Indemnification.	44
16.8	Insurance.	45
16.9	Limitation of Liability.	45
17	Assignment	45
17.1	Assignment.	45
18	Notices	45
18.1	Notices.	45
19	Miscellaneous	47
19.1	Force Majeure.	47
19.2	No Partnership or Joint Venture.	47
19.3	Execution In Counterparts.	47
19.4	Governing Law.	47
19.5	Waiver Of Breach.	47
19.6	Severability.	48
19.7	Entire Agreement.	48
19.8	Currency.	48
19.9	Form of Payments.	48
19.1	Good Faith.	48
20	Dispute Resolution	48
20.1	Internal Resolution.	48
20.2	Arbitration.	49
21	Performance	49
21.1	Performance.	49

Appendix A OPKO Patents

Schedule 2.2 Grant Lease-Back License Option

Schedule 6.1(d) Other Licensees, Contract Manufacturers and Suppliers

Schedule 9.1 Terms of Supply Agreement

Schedule 13.3 Press Release

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Schedule 16.2(a) Representations and Warranties of OPKO

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LICENSE AGREEMENT

This LICENSE AGREEMENT (this “**Agreement**”) is entered into and effective as of the 17th day of June 2021 (the “**Effective Date**”), by and among EIRGEN PHARMA LIMITED, an entity formed under the laws of Ireland with registered seat at Westside Business, Old Kilmeaden, Waterford, Ireland (“**OPKO**”), which is an indirect wholly-owned subsidiary of OPKO Health, Inc., a Delaware corporation (“**OPKO Parent**”), on the one hand, and NICOYA Macau Limited, a Macau corporation (“**Nicoya**,” or “**Licensee**”), on the other hand. OPKO and Licensee are each referred to herein by name or as a “**Party**” or, collectively, as “**Parties**.”

Recitals

A. OPKO Parent is a diversified healthcare company that, through its pharmaceutical division and Affiliates, commercializes the Product (as hereinafter defined), directly or through licensees in several jurisdictions throughout the world.

B. Licensee is a pharmaceutical company engaged in the research, development and commercialization of pharmaceutical products in the Licensee Territory.

C. OPKO and its Affiliates desire to license its rights to the Product to Licensee in the Field in the Licensee Territory, all on the terms and subject to the conditions set forth in this Agreement.

D. Licensee desires to offer to sell, sell and have sold the Product in the Field in the Licensee Territory, and OPKO is willing to grant Licensee the right to conduct such activities, all on the terms and subject to the conditions of this Agreement.

Agreement

1. Definitions; Interpretation.

When used in this Agreement, the following terms shall have the meanings set forth in this Section 1.1.

“**Accounting Standards**” means International Financial Reporting Standards (IFRS), in each case as applicable and consistently applied by the relevant Person.

“**Adverse Event(s)**” means those events as defined by the FDA and published in the U. S. Code of Federal Regulations, as amended from time to time and published in the Federal Register, or by another applicable Regulatory Authority or any similar definitions under laws within the Licensee Territory relating to adverse drug experiences relating to the use of the Product in the Licensee Territory.

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“**Affiliate**” means any Person that, on the Effective Date or at any time during the Term, directly or indirectly through one (1) or more intermediaries controls, is controlled by or is under common control with a Party, but only while that Person directly or indirectly through one (1) or more intermediaries controls, is controlled by or is under common control with a Party. For purposes of this definition, a Person shall be deemed to “control” another Person if it (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock (or such lesser percentage which is the maximum allowed to be owned by a Person in a particular jurisdiction) of such other Person, or has other comparable ownership interest with respect to any Person other than a corporation, or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the Person.

“**Agreement Year**” means each twelve (12) month period commencing on January 1 and ending on December 31 during the Term; provided, that the first Agreement Year during the Term shall commence on the Effective Date and end on December 31, and the last Agreement Year during the Term shall commence on January 1 and end on the effective date of expiration or termination of the Term.

“**Applicable Law**” means any law (including common law), statute, rule, regulation, order, judgment, or ordinance of any Governmental Authority, including those concerning environmental, health, and safety matters, applicable to either Party in its respective territory. For clarity, Applicable Law shall include regulations applicable to a Party’s activities related to this Agreement, such as Good Clinical Practices.

“**Business Day**” means a day on which commercial banks are open for business in New York City and **Beijing**, China. References in this Agreement to “days” other than Business Days shall mean calendar days.

“**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

“**Change of Control**” shall occur if: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of a Party, or if the percentage ownership of such Person or entity in the voting securities of a Party is increased through stock redemption, cancellation or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than fifty percent (50%) of the total voting power of all of the then outstanding voting securities of a Party; (b) a merger, consolidation, recapitalization or reorganization of a Party is consummated, other than any such transaction which would result in stockholders or equity holders of such Party immediately prior to such transaction, owning, directly or indirectly, at least fifty percent (50%) of the outstanding securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the stockholders or equity holders of a Party approve a plan of complete liquidation of such Party, or an agreement for the sale or disposition by such

Party of all or substantially all of such Party's assets, other than pursuant to a transaction described above or to an Affiliate; (d) individuals who, as of the date hereof, constitute the Board of Directors of a Party (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the Board of Directors of such Party (provided, however, that any individual becoming a director subsequent to the date hereof whose election, or nomination for election by such Party's shareholders, was recommended or approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board); or (e) the sale or transfer to a Third Party of all or substantially all of such Party's assets is effected.

"**CNY**" means Chinese Yuan Renminbi.

"**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective, those reasonable and good faith efforts and resources to accomplish such objective as [***] would normally use to accomplish a similar objective under similar circumstances. With respect to any efforts relating to the Regulatory Approval and/or commercialization of a Product, generally in the Licensee Territory, such Party will be deemed to have exercised Commercially Reasonable Efforts if such Party has exercised those efforts normally used by [***], in the [***], with respect to a compound, product or product candidate which is of similar market potential in the Licensee Territory and which is at [***] or [***]. With respect to any efforts to commercialize a Product, the Parties acknowledge and agree that Licensee would not have made Commercially Reasonable Efforts to commercialize a Product if it [***] or to [***].

"**Competitive Product**" means any pharmaceutical product that: (a) is marketed in the Licensee Territory by a Third Party; (b) is a [***]; and (c) is [***].

"**Compound**" means calcifediol (25-hydroxyvitamin D₃) and any salt thereof, as well as any solvates of calcifediol or any of its salts (including, but not limited to, calcifediol monohydrate).

"**Control**" means, with respect to any Patent or other intellectual property right (including know-how, trade secrets and data), ownership thereof and/or possession of the ability to grant the licenses or sublicenses as provided herein without violating the terms of any agreement or other arrangement with any Third Party or being obligated to pay any royalties or other consideration therefor, but excluding any Patent or other intellectual property right (including know-how, trade secrets and data) that comes into the Control of either Party pursuant to a Change of Control of such Party.

"**Cover(ed)**" means, with respect to any issued Patent and the subject matter at issue, that, but for a license granted under such patent, the manufacture, development, use, sale, offer for sale or importation of the subject matter at issue would infringe such patent, or in the case of

a patent application, would infringe a claim of such patent application if it were to issue in the form then currently being prosecuted.

“**Drug Approval Application**” means an application for marketing authorization or clearance required to be approved before commercial sale or use of a Product as a drug in a regulatory jurisdiction (i.e., Investigational New Drug Application, New Drug Application or equivalent).

“**FDA**” means the United States Food and Drug Administration and any successor agency thereto.

“**Field**” means the use of the Product for the treatment or prevention of the Initial Indications.

“**First Commercial Sale**” means, with respect to each Product, after all necessary Regulatory Approvals by the appropriate Regulatory Authority(ies), the first sale of Product in the Licensee Territory by Licensee, any of its Affiliates or any permitted Sublicensee to a Third Party for end use or consumption of such Product. For clarity, a First Commercial Sale shall not be deemed to have occurred if the first sale of a Product is a sale or other distribution for clinical and pre-clinical research and trials, distribution of a promotional sample, a compassionate use sale, a sale under an indigent patient program or a named patient sale.

“**Generic Product**” means, with respect to a Product in a Region, any pharmaceutical product that (a) (i) contains the same active pharmaceutical ingredient(s) as such Product, (ii) is in the same form and format as such Product, and (iii) is approved by the Regulatory Authority in such Region based on reference to data contained in an earlier regulatory filing; and (b) is sold in such Region by a Third Party that is not a Sublicensee and such Third Party did not purchase such Product or Compound from Licensee or its Affiliates or Sublicensees.

“**Good Clinical Practices**” means all applicable good clinical practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other applicable guidelines for good clinical practice for clinical trials on medicinal products, (b) the Declaration of Helsinki (2004), as last amended at the 52nd World Medical Association General Assembly in October 2000, and any further amendments or clarifications thereto, and (c) the equivalent Applicable Laws in any relevant country or region where the clinical trials at issue are being conducted, each as may be amended and applicable from time to time and, in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects. For clarity, to the extent there is any inconsistency between the foregoing items (a), (b) and (c), the last item (c) shall control.

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“**Government Official**” means (a) any elected or appointed government official (e.g., a member of a ministry of health), (b) any employee or Person acting for or on behalf of a government official, Governmental Authority, or other enterprise performing a governmental function, (c) any political party, candidate for public office, officer, employee, or Person acting for or on behalf of a political party or candidate for public office, and (d) any employee or Person acting for or on behalf of a public international organization (e.g., the United Nations). For clarity, healthcare providers employed by government-owned hospitals will also be considered Government Officials.

“**Governmental Authority**” means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

“**Initial Indications**” means the treatment or prevention of secondary hyperparathyroidism (“**SHPT**”) in non-dialysis (“**ND**”) and hemodialysis (“**HD**”) chronic kidney disease patients.

“**Initiation**” means, with respect to a clinical trial, the first dosing in the first patient in such clinical trial.

“**Joint Patent**” means any Patent that Covers a Joint Invention.

“**Licensee Patents**” means all Patents that Cover a Licensee Invention. Upon the request of OPKO, Licensee shall provide to OPKO a list of the then-current Licensee Patents. For the avoidance of doubt, Licensee Patents do not include OPKO Patents.

“**Licensee Technology**” means all Technology that is developed or generated or otherwise becomes Controlled by Licensee or its Affiliates or Sublicensees during the Term. For the avoidance of doubt, Licensee Technology does not include OPKO Technology.

“**Licensee Territory**” means greater China, which includes the People’s Republic of China (the “**PRC**”), the Hong Kong Special Administrative Region of the PRC (“**Hong Kong**”), the Macau Special Administrative Region of the PRC (“**Macau**”), and the Republic of China (“**Taiwan**”). Each of the PRC, Hong Kong, Macau and Taiwan is a “**Region**” for the purposes of Regulatory Approval.

“**Manufacturing Cost**” means, with respect to the Product supplied hereunder, the direct and indirect costs incurred by OPKO or its Affiliates determined in accordance with the Accounting Standards and consistent with OPKO’s internal accounting practices, consistently applied, for the manufacture and supply of Product (provided that any such indirect costs are reasonably allocable to the manufacture and supply of Product in accordance with the Accounting Standards and consistent with OPKO’s internal accounting practices, consistently applied), which costs may include:

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(a) the cost of active pharmaceutical ingredients, materials, components, supplies and other resources directly or indirectly consumed for the manufacture, testing, and supply of Product, in each case including freight, insurance, shipping, packaging (and including the cost of packaging) and other similar costs associated with acquiring such items;

(b) labor (including salaries, wages and current period employee benefits, but specifically excluding expenses associated with stock options or other equity-based or deferred compensation), including management salary and benefits reasonably allocable to the manufacture, testing, packaging (as applicable) and supply of Product;

(c) the net cost or credit of any value-added taxes or duties actually paid or utilized (and not reimbursed or reimbursable) on account of the Product;

(d) out-of-pocket expenses paid to a Third Party for the manufacture, testing and supply of Product, including transportation costs, customs, duty and transit insurance costs;

(e) scraps and batches resulting from the manufacture and supply of the Product that do not conform to the applicable specifications to the extent that such non-conformities are not caused by [***];

(f) costs for quality control/assurance (including the costs of quantities destroyed in quality control testing) of the Product, including the costs of inspection, rejection and return of components, materials or services;

(g) costs reasonably allocable to ensuring manufacture and supply operations for Product comply with Applicable Laws, including costs for obtaining and maintaining permits, registrations, and authorizations required by Governmental Authorities;

(h) other costs reasonably allocable to the manufacture and supply of Product, including allocable occupancy, depreciation and amortization of facilities, allocable facilities costs, general and administrative costs, and other overhead; and

(i) the amount of any royalty payable by OPKO to Catalent Pharma Solutions, LLC (“**Catalent**”) with respect to the use of Catalent intellectual property rights or technology that is used to manufacture the Product.

“**Marketing Material**” means the written, printed, electronic or graphic materials related to strategy, communications and programs associated with the marketing or promotion of the Product, including such strategy, communications, programs and any promotional and marketing materials that (a) specifically identify or describe the Product or (b) otherwise support the Product or raise awareness of the Product.

“**Net Sales**” means the gross amounts invoiced by Licensee, its Affiliates and their Sublicensees (each a “**Selling Party**”) for sales of Product to Third Parties in the Licensee

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Territory during the Royalty Term, less the following deductions to the extent actually taken, determined in accordance with the Accounting Standards and consistent with each Selling Party's internal accounting practices, consistently applied:

(a) bad debts and uncollectable invoiced amounts relating to sales of the Product that are [***] in accordance with the Accounting Standards, consistently applied; provided, that any [***] shall be [***] for the [***] and any [***] will be included in the current Net Sales calculation;

(b) sales returns and allowances actually paid, granted or accrued, including trade, quantity and cash discounts and other adjustments, including those granted on account of price adjustments, returns, rebates, chargebacks or similar payments granted or given to wholesalers or other institutions;

(c) adjustments arising from consumer discount programs or other similar programs;

(d) clawback taxes, customs or excise duties, valued-added taxes, sales taxes, consumption taxes and other taxes (except income taxes) or duties relating to sales, any payment in respect of sales to any Governmental Authority, or with respect to any government subsidized program or managed care organization, each to the extent applicable and not already reflected in the amount invoiced; and

(e) freight, distribution cost, [***] customs dues, insurance and transportation costs for the Product to the extent included in the amount invoiced, provided, that in no event shall deductions under this subsection (e) exceed [***] of gross sales for any applicable period.

Net Sales shall be determined from books and records maintained in accordance with the Accounting Standards and each Selling Party's internal accounting practices, as consistently applied, with respect to sales of any Product.

The sale of Products to Licensee's Affiliates and its Sublicensees shall not be deemed as a "sale" within the meaning of this definition except to the extent that such Affiliates and Sublicensees are end users of Products.

Net Sales will not include Products transferred for use in connection with clinical trials or other development activities, pre-clinical research and trials, promotional use (including samples), compassionate sales or use or indigent programs.

If a Product is sold as a combination therapy comprised of a Product and one or more products containing therapeutically-active ingredients (other than Compound) sold under a single Regulatory Approval and priced as a unit at a single price (a "**Combination Product**"), then "**Net Sales**," for purposes of determining Royalty Payments on the Combination Product, shall be calculated as follows:

(1) when the components of the Combination Product are sold separately in the Licensee Territory, by multiplying the Net Sales of the Combination Product (calculated before application of this formula) by the fraction $A/(A+B)$, where A is the price of the Product sold separately, and B is the price of the component of the Combination Product other than the Product (the “**Supplemental Component**”) in the Licensee Territory of the Supplemental Component(s); or

(2) when either the Product or the Supplemental Component are not sold separately in the Licensee Territory, the Parties shall negotiate in good faith to determine an appropriate allocation of Net Sales for the Product and the Supplemental Component.

“**New Drug Approval**” means an approval by a Governmental Authority of a Drug Approval Application.

“**OPKO Patents**” means all Patents in the Licensee Territory that (a) are Controlled by OPKO or its Affiliates as of the Effective Date or become Controlled by OPKO or its Affiliates during the Term, and (b) have a claim that Covers the Product, or a use of the Product. The list of OPKO Patents as of the Effective Date is set forth in Appendix A attached hereto and, upon request of Licensee (such request to be made no more than once every six (6) month-period), OPKO shall provide to Licensee a list of the then-current OPKO Patents. For the purposes of this Agreement, OPKO Patents shall not include Other Licensee Patents.

“**OPKO Technology**” means all Technology that (a) is Controlled by OPKO or its Affiliates as of the Effective Date, or (b) is developed or generated, or otherwise becomes Controlled by OPKO or its Affiliates during the Term. For the purposes of this Agreement, OPKO Technology shall not include Other Licensee Technology.

“**OPKO Territory**” means the entire world other than the Licensee Territory.

“**OPKO Trademark(s)**” means Rayaldee[®] calcifediol ER capsules, a trademark Controlled by OPKO in the Licensee Territory, and any other trademark, service mark or logo developed, applied for, registered, or to be applied for or registered by OPKO or its Affiliates for use in connection with the sale of the Product in the Licensee Territory.

“**Other Licensee(s)**” means any Third Party licensee of OPKO or its Affiliates (a) to which OPKO or its Affiliates have granted rights to the Compound and/or Product under OPKO Patents and/or OPKO Technology outside the Territory and/or outside the Field, and/or (b) from which OPKO or its Affiliates have received a grant of rights to the Compound and/or Product under Other Licensee Patents and Other Licensee Technology.

“**Other Licensee Patents**” means all Patents of an Other Licensee in the Licensee Territory to the extent related to the Compound or Product to which OPKO or its Affiliates have obtained rights, solely to the extent OPKO or its Affiliates has the right to grant a license to Licensee under the terms of such rights.

“**Other Licensee Technology**” means all material Technology of an Other Licensee in the Licensee Territory to the extent related to the Compound or Product to which OPKO or its Affiliates have obtained rights, solely to the extent OPKO or its Affiliates has the right to grant a license to Licensee under the terms of such rights.

“**Patents**” means (a) all patents and patent applications in any country or jurisdiction in the relevant territory, and (b) any substitutions, divisions, continuations, continued prosecution applications, continuations-in-part, provisional applications, priority applications (including rights of priority), reissues, renewals, registrations, additions, confirmations, re-examinations, extensions, validations, supplementary protection certificates and the like of any such patents or patent applications.

“**Person**” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

“**Phase III Clinical Trial**” means a human clinical trial of a compound or product for an indication on a sufficient number of subjects that is designed to establish that the compound or product is safe and efficacious for its intended use, and to determine warnings, precautions and adverse reactions that are associated with the compound or product in the dosage range to be prescribed, and to support Regulatory Approval of the compound or product for such indication, as more fully defined in 21 C.F.R. §312.21(c), or its successor regulation, or the equivalent in any foreign country.

“**Product**” means a modified, extended, sustained release, or any release other than immediate release, pharmaceutical product that contains a Compound as the sole therapeutically active substance, in all dosage forms and formulations, contained in or Covered by the OPKO Patents and/or OPKO Technology.

“**Regulatory Approval**” means any approvals, product and/or establishment licenses, registrations, permits, or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity or Regulatory Authority, necessary for the manufacture, distribution, use, storage, importation, export, transport, marketing and sale of the Product in a regulatory jurisdiction.

“**Regulatory Authority**” means any national, supra-national, regional, state or local regulatory agency, department, bureau or other governmental entity responsible for issuing any technical, medical and scientific licenses, registrations, authorizations and/or approvals of the Product that are necessary for the manufacture, distribution, use, storage, importation, export, transport and sale of the Product in a regulatory jurisdiction.

“**Sublicensee**” means an Affiliate or Third Party that has been granted a sublicense by a Party as permitted under Sections 2.1 or 2.2 of this Agreement.

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“**Technology**” means all information, in any form (including electronic form), that is not in the public domain and that is necessary or useful for the development, regulatory approval or commercialization of the Compound or the Product in the Licensee Territory. Examples of Technology are, to the extent relating to the Compound or Product, biological, chemical, pharmacological, toxicological, medical or clinical, analytical, quality, manufacturing, research, regulatory and sales and marketing information. As used in this Agreement, the term “material Technology” refers to written (including electronic) information that is necessary for the development, Regulatory Approval or commercialization (but not including sales and marketing information) of the Compound or the Product in the Licensee Territory.

“**Third Party(ies)**” means any Person other than OPKO and its Affiliates, and Licensee and its Affiliates.

“**Valid Claim**” means a claim of (a) an issued and unexpired patent included in the OPKO Patents or Other Licensee Patents that has not been (i) held unpatentable or unenforceable by a final decision of a court or other governmental body of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, or (ii) abandoned or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise, or (b) a pending patent application included in the OPKO Patents or Other Licensee Patents that continues to be prosecuted in good faith and has not been pending for longer than [***].

In addition to the defined terms set forth above, the following capitalized terms shall have the meaning ascribed to such terms in the Sections of this Agreement identified below:

Capitalized Term	Section
Agreement	Preamble
Alliance Manager	8.4(a)
Applicable Percentage	4.3
Bulk Product	9.1
[***]	2.6
Catalent	1.1
Claim	12.3(b)
Combination Product	1.1
Committee	9.1(a)
Confidential Information	13.2
Dispute	20.1
Effective Date	Preamble
Extended Payment Term	3.2
Grant-back License Option	2.2(a)(ii)
Incumbent Board	1.1
Indemnitee	16.7

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Inventions	12.1(a)
Joint Inventions	12.1(b)
JSC	8.1(a)
Licensee	Preamble
Licensee Inventions	12.1(c)
Licensee Prosecution Patents	12.2(b)
Licensee Trademark	7.2(c)
Losses	16.5
Nicoya	Preamble
[***]	12.12(b)
OPKO	Preamble
OPKO Inventions	12.1(a)
OPKO Prosecution Patents	12.2(a)
Parties	Preamble
Party	Preamble
Party Vote	8.1(c)
Paying Party	4.8(a)
Pharmacovigilance Agreement	10.2
Quality Agreement	9.1
Recall	6.5
Receiving Party	4.8(a)
Regulatory Action	6.4
Relevant Patents	12.12(a)
ROFR	2.6
ROFR Exercise Notice	2.6
ROFR Negotiation Period	2.6
ROFR Notice	2.6
Royalty Payments	4.3
Royalty Term	4.4
SHPT	1.1
Supplemental Component	1.1
Supply Agreement	9.1
Term	3.1

1.2 Interpretation.

(a) The words “hereof,” “herein” and “hereunder” and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement, and section, schedule, exhibit and appendix references

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are to this Agreement unless otherwise specified. The words “will” and “shall” shall have the same meaning. The meaning of defined terms shall be equally applicable to the singular and plural forms of the defined terms. Masculine, feminine and neuter pronouns and expressions shall be interchangeable. The words “include,” “includes” and “including” are not limiting and shall be deemed to be followed by the phrase “without limitation” or “without limiting,” whether or not expressly stated.

(b) Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. In the computation of periods of time from a specified date to a later specified date, the word “from” means “from and including”; the words “to” and “until” each mean “to but excluding,” and the word “through” means “to and including.”

(c) References to agreements and other contractual instruments shall be deemed to include all subsequent amendments and other modifications thereto, but only to the extent such amendments and other modifications are not expressly prohibited by the terms of this Agreement. References to this Agreement are to this Agreement as in effect as of the relevant time, and mean this Agreement as a whole, including all schedules, exhibits, or appendices hereto, which form part of the operative provisions of this Agreement, in each case, as amended or otherwise modified in accordance with the terms hereof.

(d) Unless otherwise specified, references to statutes or regulations are to be construed as including all statutory and regulatory provisions consolidating, amending or replacing the statute or regulation, and references to a particular Applicable Law include all rules and regulations promulgated by Governmental Authorities thereunder, whether or not expressly stated.

(e) The captions and headings of this Agreement are for convenience of reference only and shall not affect the construction of this Agreement.

(f) References in this Agreement to “Product-by-Product,” mean that each of the following shall be deemed to be a single Product: (i) all Products marketed or sold [***]; and (ii) each Combination Product; provided, that a [***] with the same active ingredients shall be regarded as [***].

(g) This Agreement has been prepared jointly by the Parties, and the provisions contained herein shall not be construed or interpreted for or against any Party because such Party drafted or caused such Party’s legal representatives to draft any provision contained herein.

2. Grant of Rights

2.1 OPKO Patents, OPKO Technology, Other Licensee Patents and Other Licensee Technology.

(a) Subject to the terms and conditions of this Agreement, OPKO hereby grants to Licensee and, to the extent any such rights are Controlled by an Affiliate of OPKO, OPKO shall cause such Affiliate to grant to Licensee an exclusive (even as to OPKO and its Affiliates), sublicenseable (subject to Section 2.1(c)), royalty-bearing license under the OPKO Patents and OPKO Technology to, research and develop (subject to the last sentence of this Section 2.1), use, distribute, market, promote, offer to sell, sell, have sold, import, label, package and commercialize Products in the Field in the Licensee Territory. The right to research and develop is solely for the purpose of seeking and/or maintaining Regulatory Approval from Regulatory Authorities in the Territory for the Initial Indication.

(b) To the extent expressly permitted by an agreement with Other Licensees, OPKO hereby grants to Licensee, and, to the extent any such rights are Controlled by an Affiliate of OPKO, OPKO shall cause such Affiliate to grant to Licensee, the same licenses set forth in Section 2.1(a) under Other Licensee Patents and Other Licensee Technology.

(c) Licensee may sublicense its rights under Section 2.1(a) and/or Section 2.1(b) to its Affiliates without OPKO's prior written consent, or to any Third Party with OPKO's prior written consent, which shall not be unreasonably withheld, delayed or conditioned. With respect to each sublicense that Licensee proposes to grant to a Third Party, Licensee shall notify OPKO in writing at least [***] Business Days in advance of the grant, including a description of the rights to be granted and the identity of the proposed Third Party sublicensee. For the avoidance of doubt, [***] shall not be considered to be sublicensees for the purposes of this Section 2.1(c). If Licensee does not receive a written reply from OPKO within [***] Business Days, it shall be deemed that OPKO agree this sublicense. Licensee shall ensure that: (A) each Sublicensee accepts all applicable material terms and conditions of this Agreement and shall use Commercially Reasonable Efforts to ensure that each Sublicensee complies with all applicable material terms and conditions of this Agreement; (B) each sublicense shall (1) be subject to an appropriate written agreement imposing on each Sublicensee the terms and conditions of this Agreement, including all restrictive covenants set forth in this Agreement, (2) contain a provision prohibiting such Sublicensee from further sublicensing its rights, and (3) not in any way diminish, reduce or eliminate any of Licensee's obligations under this Agreement. Licensee shall provide to OPKO within [***] Business Days of such grant, a copy of each sublicense agreement (after redacting any financial information and other provisions that are not necessary to understand the scope of the sublicense granted to such Sublicensee or to confirm that such sublicense is in compliance with the terms of this Agreement, including this Section 2.1(c)). For the avoidance of doubt, Licensee will remain directly responsible for all amounts owed to OPKO and the performance of all obligations under this Agreement. Licensee hereby expressly waives any requirement that OPKO exhaust any right, power or remedy, or proceed against a

Sublicensee for any obligation or performance hereunder prior to proceeding directly against Licensee.

(d) OPKO hereby grants to Licensee a right of first refusal to obtain an exclusive license, at any time during the Term, under the OPKO Patents, OPKO Technology, Other Licensee Patents and/or Other Licensee Technology to research and develop (as set forth in Section 2.1(a)), use, have used, distribute, market, promote, offer to sell, sell, have sold, import, label, package and otherwise commercialize the Compounds and Products outside the Field in the Licensee Territory.

2.2 Licensee Patents and Licensee Technology.

(a) Subject to the terms and conditions of this Agreement and Schedule 2.2, Licensee hereby grants to OPKO and, to the extent any such rights are Controlled by an Affiliate of Licensee, Licensee shall cause such Affiliate to grant to OPKO:

(i) a non-exclusive, sublicenseable (subject to Section 2.2(b)), fully paid-up, royalty-free (subject to Section 15.4(a)(ii)), perpetual license under the Licensee Patents and Licensee Technology to [***], develop, make, have made, use, sell, import, export, offer to sell, sell and have sold Compounds and Product (A) in all fields of use in the OPKO Territory, and (B) outside the Field in the Licensee Territory; and

(ii) an exclusive [***] to the Licensee Patents and Licensee Technology set forth in Section 2.2(a)(i) above to [***] (the “**Grant-back License Option**”), on [***], which may include the payment by OPKO of royalties to Licensee.

(b) OPKO may sublicense its rights under Section 2.2(a) to (i) its Affiliates freely, and (ii) an Other Licensee, provided, that the Other Licensee permits OPKO to sublicense the Other Licensee’s intellectual property rights to Licensee on substantially the same basis as the license that the Other Licensee would be receiving from OPKO, as the context requires. Notwithstanding the grant by OPKO of a sublicense to Licensee Patents and Licensee Technology, OPKO will remain directly responsible to Licensee for any actions by the Sublicensee that violate the scope of the license and, in connection therewith, OPKO hereby expressly waives any requirement that Licensee exhaust any right, power or remedy, or proceed against a Sublicensee for any obligation or performance hereunder prior to proceeding directly against OPKO.

2.3 Retained Rights.

Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel or otherwise, other than the license rights that are expressly granted under this Agreement. For the avoidance of doubt, OPKO retains all of its rights under its Control with respect to Compounds, Product, the OPKO Patents, the OPKO Technology and the OPKO Trademarks in order to (a) make and have made Compounds and

Product in the Licensee Territory, (b) conduct [***] and pre-clinical development of Compounds and Product in the Field in the Licensee Territory, and (c) develop, use, sell, import, export, offer to sell, sell and have sold Compounds and Product (i) in the OPKO Territory in all fields of use, and (ii) in the Licensee Territory in all fields of use other than the Field, subject to Section 2.1(d).

2.4 Subcontracting.

Subject to the limitations on sublicenses set forth in Section 2.1(c), [***]. Licensee shall be responsible for the performance of all actions, agreements and obligations to be performed by any of its subcontractors under the terms and conditions of this Agreement, and shall use Commercially Reasonable Efforts to cause its subcontractors to comply with the provisions of this Agreement in connection with such performance. Any breach by Licensee's subcontractors of any of Licensee's obligations under this Agreement shall be deemed to be a breach by Licensee, and OPKO may proceed directly against Licensee without any obligation to first proceed against Licensee's subcontractors.

2.5 Ex-Territory and Ex-Field Activities.

(a) Licensee hereby covenants and agrees that, during the Term, Licensee shall not (and shall cause its Affiliates, Sublicensees and subcontractors not to), either itself or through a Third Party, market, promote or actively offer for sale the Product (i) outside the Field in the Licensee Territory, or (ii) in any field of use in the OPKO Territory. Without limiting the generality of the foregoing, with respect to the OPKO Territory, Licensee shall not (A) engage in any promotional activities relating to the Product directed solely to customers in the OPKO Territory, or (B) solicit orders from any purchaser that intends to, or Licensee has a reasonable basis for believing may intend to, distribute the Product in the OPKO Territory. To the extent permitted by Applicable Law, including applicable antitrust laws, if Licensee receives any order for the Product under the preceding subsection (B), then Licensee shall immediately refer that order to OPKO and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the Product under such order. If Licensee should reasonably know that a customer or distributor is engaged itself or through a Third Party in the sale or distribution of the Product in the OPKO Territory or outside the Field within the Licensee Territory, then Licensee shall (1) within [***] Business Days of gaining knowledge of such activities, notify OPKO regarding such activities and provide all information available to Licensee that OPKO may reasonably request concerning such activities, and (2) take Commercially Reasonable Efforts (including cessation of sales to such customer) necessary to limit such sale or distribution, unless otherwise agreed in writing by the Parties.

(b) OPKO hereby covenants and agrees that, during the Term, OPKO shall not (shall cause its Affiliates not to, and shall use reasonable efforts to cause its Other Licensees, sublicensees and subcontractors not to), either itself or through a Third Party, market, promote or actively offer for sale the Product for use in the Field in the Licensee Territory. Without limiting

the generality of the foregoing, with respect to the Licensee Territory, OPKO shall not (i) engage in any promotional activities relating to the Product for use in the Field directed solely to customers in the Licensee Territory, or (ii) solicit orders from any purchaser that intends to, or OPKO has a reasonable basis for believing may intend to, distribute the Product in the Licensee Territory for use in the Field. To the extent permitted by Applicable Law, including applicable antitrust laws, if OPKO receives any order for the Product under the preceding subsection (B), then OPKO shall immediately refer that order to Licensee and shall not accept any such order or deliver or tender (or cause to be delivered or tendered) the Product under such order. If OPKO should reasonably know that a customer or distributor is engaged itself or through a Third Party in the sale or distribution of the Product for use in the Field in the Licensee Territory, then OPKO shall (A) within [***] Business Days of gaining knowledge of such activities, notify Licensee regarding such activities and provide all information available to OPKO that Licensee may reasonably request concerning such activities, and (B) take Commercially Reasonable Efforts (including cessation of sales to such customer) necessary to limit such sale or distribution, unless otherwise agreed in writing by the Parties.

2.6 Licensee Right of First Refusal for [***] Products.

OPKO hereby grants to Licensee a right of first refusal (the “**ROFR**”) to obtain an [***] to develop and commercialize in the Licensee Territory any pharmaceutical product (other than a Product) containing [***] (including, but not limited to [***]) in any formulation (a “[***]”). If at any time during the Term, OPKO or its Affiliate intends to enter into discussions or negotiations with a Third Party with respect to any license to commercialize the [***] in the Licensee Territory, OPKO shall provide written notice of its intention to Licensee (the “**ROFR Notice**”). Licensee shall have the right to exercise the ROFR by delivery to OPKO of a written notice of exercise (the “**ROFR Exercise Notice**”) within [***] days after the date it receives the ROFR Notice. If Licensee exercises the ROFR by delivery to OPKO of the ROFR Exercise Notice, then the Parties shall have [***] days from the date of the ROFR Exercise Notice (the “**ROFR Negotiation Period**”) to negotiate in good faith the terms of such [***] license, which terms shall be commercially reasonable for an exclusive license of such type. If (a) Licensee has not delivered an ROFR Exercise Notice to OPKO within the [***] day period set forth above, (b) Licensee notifies OPKO prior to the expiration of the [***] day period set forth above that it does not intend to exercise the ROFR, or (c) the Parties are unable to reach agreement on the economic or other terms for such exclusive license prior to the expiration of the ROFR Negotiation Period, then OPKO shall have the right to license to a Third Party the right to develop and commercialize the [***] in the Licensee Territory.

3. Term

3.1 Term.

The term of this Agreement shall commence on the Effective Date and shall continue on a Product-by-Product basis until the expiration of all Royalty Terms and Extended Payment Terms under this Agreement, unless earlier terminated pursuant to Section 16.1 (the “**Term**”).

3.2 Expiration.

Upon the expiration of the Royalty Term (and not including any early termination of this Agreement under Article 15) with respect to a Product, the licenses granted to Licensee under Section 2.1 shall become fully-paid, royalty-free, perpetual and non-exclusive. If Licensee or its Affiliates or Sublicensees use the OPKO Trademarks in the Licensee Territory after the expiration of the Royalty Term for a Product, then Licensee’s license to use the OPKO Trademarks shall remain exclusive so long as Licensee pays OPKO a royalty of [***] of any Net Sales in the Licensee Territory (the “**Extended Payment Term**”).

4. Fees and Payments

4.1 Upfront Payment.

In consideration for the rights granted to Licensee in this Agreement, Licensee shall pay to OPKO a non-refundable and non-creditable payment of Five Million United States Dollars (\$5,000,000) (the “Upfront Payment”) within [***] days after the Effective Date.

4.2 Milestone Payments.

As additional consideration for the rights granted to Licensee in this Agreement, Licensee shall pay to OPKO the non-refundable and non-creditable milestone payments in the amounts and upon the occurrence of the milestone events for the Product set forth below.

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Milestone Event	Milestone Payment (in United States Dollars)
1. The first to occur of (A) Initiation of [***] Phase III Clinical Trial for the prevention or treatment of SHPT in ND patients in the Licensee Territory, <u>or</u> (B) the first anniversary of the Effective Date.	\$5,000,000
2. The Initiation of the [***] for the prevention or treatment of [***] in the Licensee Territory.	[***]
3. [***] in the Licensee Territory for the prevention or treatment of [***]	[***]
4. [***] in the Licensee Territory for [***]	[***]
5. First time aggregate Net Sales of all Products in the Licensee Territory exceed [***] in an Agreement Year	[***]
6. First time aggregate Net Sales of all Products in the Licensee Territory exceed [***] in an Agreement Year	[***]

Each such milestone payment shall be made within [***] days of the achievement or occurrence of the relevant milestone event. Each milestone payment will be payable only one (1) time and, for the avoidance of doubt, no more than One Hundred Twenty Million Dollars (\$120,000,000) in milestone payments shall be payable under this Section 4.2. For purposes of clarity if Net Sales of the Products in the Licensee Territory during a particular Agreement Year exceed [***], and it was the first Agreement Year in which Net Sales of the Product in the Licensee Territory exceeded [***], then Licensee would owe both the [***] and [***] milestone payments and no other milestone payments would be due in any following Agreement Year with respect to such milestone events.

4.3 Royalty Payments.

Subject to the terms and conditions of this Agreement, during the Royalty Term, Licensee shall pay to OPKO royalty payments (the “**Royalty Payments**”) on a Calendar Quarter basis in an amount equal to the aggregate annual Net Sales of Products within the Licensee Territory multiplied by the Applicable Percentage, as may be adjusted as set forth in this Agreement. The “**Applicable Percentage**” shall be as follows.

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Aggregate Net Sales of all Products in an Agreement Year	Applicable Percentage
For the portion up to and including [***]	[***]
For the portion in excess of [***] up to and including [***]	[***]
For the portion in excess of [***] up to and including [***]	[***]
For the portion in excess of [***]	[***]

In the case that the annualized royalty rate during a particular Agreement Year is more than the Applicable Percentage, the corresponding overpayment received by OPKO shall be credited to Licensee against subsequent Royalty Payments; and in the case that the annualized royalty rate during a particular Agreement Year is less than that the Applicable Percentage, Licensee shall pay the difference within [***] days after determination of such difference.

4.4 Royalty Term.

The Royalty Payments due under Section 4.3 will be payable on a Product-by-Product basis beginning from the First Commercial Sale in Region and continuing until the last of the following:

- (a) expiration of the last to expire Valid Claim Covering the Product in the Region;
- (b) expiration of all regulatory and data exclusivity applicable to the Product in the Region; and
- (c) on a Product-by-Product basis, ten (10) years from the First Commercial Sale for such Product in the Region.

The period during which the Royalty Payments for a Product are due is referred to as the “**Royalty Term**”.

4.5 Royalty Reductions and Credits.

(a) If required under Applicable Law then with respect to any Product, Royalty Payments are owed solely on account of Sections 4.4(b) or 4.4(c), and for clarity, not on account of Section 4.4(a), then the Royalty Payments for such Product shall be [***] of the amounts that would otherwise be due under Section 4.3.

(b) If, in a Region during the Royalty Term for a Product, sales of all Generic Products of such Product in such Region in a Calendar Quarter exceed [***], but is no more than [***], of the [***] of such [***] plus the [***] of such [***] to such [***] in such Region, then

the royalty rate payable by Licensee to OPKO with respect to Net Sales of the Product in such Region for such Calendar Quarter shall be [***] of the otherwise applicable rate. If, in a Region within the Territory during the Royalty Term for a Product, sales of all Generic Products to such Product in such Region in a Calendar Quarter [***] of the unit volume of all sales of such Product plus the unit volume of all sales of such Generic Products to such Product in such Region, then the royalty rate payable by Licensee to OPKO with respect to Net Sales of the Product in such Region for such Calendar Quarter shall be reduced by [***] of the otherwise applicable rate. All such determinations of the unit volume of sales shall be based upon a mutually acceptable calculation method using market share data provided by a reputable and mutually agreed upon provider, such as IMS Health.

(c) To the extent the Parties have agreed, pursuant to Section 12.12(a), that a Third Party Patent is necessary to use, import, sell, have sold, offer for sale or otherwise commercialize a Product in a particular Region, the royalties payable by Licensee to OPKO shall be [***] of the royalties payable to such Third Party licensor(s) with respect to Net Sales of the Product in such Region against the royalties otherwise payable by Licensee to OPKO with respect to Net Sales of the Product in such Region. For clarity, if the Parties have not agreed pursuant to Section 12.12(a) that Licensee is required to license the Third Party Patent, but nevertheless Licensee does so, then the Licensee shall bear [***] of such Third Party Patent.

4.6 Late Payments.

Any amount required to be paid by a Party hereunder which is not paid on the date due shall bear interest at a rate equal to the [***] as published by The Wall Street Journal for the date that payment was first due, or the maximum rate allowable by Applicable Law, whichever is [***], with such [***].

4.7 Reports, Timing and Method of Payments, and Foreign Exchange.

(a) Within [***] following the end of each Calendar Quarter commencing with the end of the first Calendar Quarter during which the First Commercial Sale occurs, Licensee shall provide OPKO with a written report setting forth its good faith estimate of (i) gross sales of Products in the Licensee Territory during the prior Calendar Quarter in local currency, (ii) Net Sales of Products in the Licensee Territory during the prior Calendar Quarter in local currency, and (iii) a calculation of the amount (including applicable exchange rate) of the Royalty Payment due to OPKO under Section 4.3 with respect to the prior Calendar Quarter, including calculation of any reductions or credits against Royalty Payments taken in accordance with Section 4.5. OPKO acknowledges that any report provided under this Section 4.7(a) shall only be an estimate and is subject to actual adjustments in the final report to be delivered under Section 4.7(b). Licensee acknowledges that any report provided under this Section 4.7(a) shall be used for OPKO's financial reports filed with the U.S. Securities and Exchange Commission.

(b) Within [***] following the end of each Calendar Quarter, commencing with the end of the first Calendar Quarter during which the First Commercial Sale occurs, Licensee shall provide OPKO with a report including (i) gross sales of Products in the Licensee Territory during the prior Calendar Quarter in local currency, (ii) Net Sales of Products in the Licensee Territory during the prior Calendar Quarter in local currency, and all calculations used to determine such Net Sales from gross sales, and (iii) a calculation of the amount (including applicable exchange rate) of the Royalty Payment due to OPKO under Section 4.3 with respect to the prior Calendar Quarter, including calculation of any reductions or credits against Royalty Payments taken in accordance with Section 4.5. Not later than [***] days following the end of each Calendar Quarter, Licensee shall pay to OPKO the Royalty Payment to which OPKO is entitled under Section 4.3 by wire transfer to OPKO's bank account designated in writing.

(c) In the event that a Party disputes an invoice or other payment obligation under this Agreement, such Party shall [***] the undisputed amount of the invoice or other payment obligation, and the Parties shall resolve such dispute in accordance with Article 20.

4.8 Taxes.

(a) Each Party shall be responsible for any income taxes payable by such Party on incomes made to it under this Agreement. Licensee shall have the right to deduct any withholding tax required to pay or withhold on behalf of OPKO from the payments pursuant to this Article 4 and other payments as long as Licensee shall provide OPKO with certified receipts of the payments of such withholding taxes duly issued by the Governmental Authorities in the Licensee Territory and shall give OPKO such assistance as may be reasonably necessary for OPKO to claim exemption from income tax in Ireland. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible, taxes payable with respect to this Agreement and that they shall use their Commercially Reasonable Efforts to cooperate and coordinate with each other to achieve such objective as allowed under Applicable Laws. To the extent that the Party making the payment under this Agreement (“**Paying Party**”) is required to deduct and withhold taxes on any payment to the other Party (“**Receiving Party**”), Paying Party shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to the other Party an official tax certificate or other evidence of such withholding sufficient to enable Receiving Party to claim credit or deduction of such payment of taxes. Receiving Party shall provide Paying Party with any completed tax forms that may be reasonably necessary in order for Paying Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. The Parties acknowledge that said tax forms have to be filed with the Governmental Authority periodically. Each Party shall cooperate with the other to the extent reasonably requested for the purpose of filing any tax returns relating to sales, use, transfer, stamp, VAT, withholding, or similar taxes, if any, levied on amounts payable hereunder.

(b) For purposes of clarity, all sums payable under this Agreement shall be exclusive of VAT. In the event that any VAT is owing in any jurisdiction in respect of any such

payment, Paying Party shall pay such VAT and the payment in respect of which such VAT is owing shall be made by Paying Party without deduction for or on account of such VAT to ensure that Receiving Party receives a sum equal to the sum which it would have received had such VAT not been due.

4.9 Currency Exchange.

If any Product sold by Licensee under this Agreement is invoiced in a currency other than U.S. dollars, all Royalty Payments by Licensee to OPKO shall be converted into U.S. dollars at the average rate of exchange for the Calendar Quarter for which payments are being remitted based on OANDA rates.

4.10 Adjustments.

If there is any major change in the pharmaceutical regulatory environment relating to the Product in the Licensee Territory (including, but not limited to, the drug pricing system and bundled payments), then upon the request of either Party, the Parties shall meet and discuss in good faith to determine whether an adjustment to the terms and conditions of this Agreement, including the financial provisions set forth in this Article 4, is appropriate.

5. Clinical Data

5.1 Data Sharing.

(a) Within [***] days after the Effective Date, OPKO shall use Commercially Reasonable Efforts to transfer to Licensee without charge to Licensee all material data and results included within the OPKO Technology and the Other Licensee Technology that is necessary or useful to obtain Regulatory Approval of the Compound and the Product in the Field in the Licensee Territory.

(b) From time to time during the Term upon the request of Licensee, OPKO shall use Commercially Reasonable Efforts to transfer to Licensee any new material data and results included within the OPKO Technology and the Other Licensee Technology that is necessary or useful to obtain or maintain Regulatory Approval of the Compound and the Product in the Field in the Licensee Territory that was not previously transferred to Licensee; provided, that any such material data and results included within the Other Licensee Technology that is provided by OPKO to Licensee under this Section 5.1(b) (i) will be provided without charge to Licensee to the extent OPKO is not required to make any payment to obtain and share such data and results, and (ii) subject to Section 16.3, will be provided to Licensee with Licensee sharing in a portion of the cost in the event OPKO is required to make a payment to obtain such data and results and such data and results are used by Licensee for purposes of obtaining Regulatory Approval for the Product in the Field in the Licensee Territory. For clarity, OPKO shall ensure that any data and results generated from clinical studies conducted jointly by OPKO and an

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. OMISSIONS ARE IDENTIFIED AS []***

Other Licensee for the treatment of SHPT in hemodialysis patients will be provided to Licensee without charge for use in the Field and the Licensee Territory.

(c) From time to time during the Term upon the request of OPKO, Licensee shall use Commercially Reasonable Efforts to transfer to OPKO all material data and results included within the Licensee Technology that is necessary or useful to obtain or maintain Regulatory Approval of a Product (i) in all fields of use in the OPKO Territory, and (ii) outside the Field in the Licensee Territory.

6. Regulatory Matters

6.1 Regulatory Filings and Regulatory Approvals.

(a) Licensee shall be responsible for preparing and filing Drug Approval Applications and seeking and maintaining Regulatory Approval for the Product in the Field in each jurisdiction in the Licensee Territory, including preparing all documentation and reports necessary in connection therewith, as well as securing data and market exclusivity where applicable in compliance with Applicable Laws in the Licensee Territory. All such Drug Approval Applications and Regulatory Approvals shall be owned by Licensee and Licensee shall promptly provide to OPKO a comprehensive summary in English and a copy in its original language of each such Drug Approval Application, Regulatory Approval and material submission to and communication with a Regulatory Authority regarding the same. Except as expressly set forth in this Agreement, all costs and expenses incurred by Licensee in connection with the preparation, filing and maintenance of Drug Approval Applications and Regulatory Approvals for the Product in the Field in the Licensee Territory shall be borne solely by Licensee. Notwithstanding the foregoing to the contrary, any costs and expenses related to the translation to English of the Drug Approval Applications, Regulatory Approvals or material communications with a Regulatory Authority in the Licensee Territory to be provided to OPKO by Licensee shall be borne by OPKO, while any costs and expenses related to the translation to Chinese of the Drug Approval Applications, Regulatory Approvals or material communications with a Regulatory Authority in OPKO Territory to be provided to Licensee shall be borne by Licensee.

(b) OPKO shall (i) make available to Licensee all information and data Controlled by OPKO, its Affiliates and Third Party contract manufacturers and suppliers that Licensee reasonably indicates to OPKO is required to file Drug Approval Applications or obtain Regulatory Approval for the Product in the Field in the Licensee Territory, (ii) make its personnel with relevant subject matter expertise available on a reasonable basis to consult with Licensee with respect thereto, and (iii) cooperate, and use Commercially Reasonable Efforts to cause its Affiliates and Third Party contract manufacturers and suppliers to cooperate, with Licensee to make changes, at Licensee's reasonable cost, to the manufacturing of the Compound and/or Product that are required in order to ensure that the Compound and/or Product supplied to

Licensee is compliant with requirements by Regulatory Authority and Applicable Laws in the Licensee Territory.

(c) If OPKO has in its possession information of the nature described in Section 6.1(b)(i) above from an Other Licensee, but does not have the right to provide this information to Licensee for its use in the Field and the Licensee Territory, then OPKO shall use Commercially Reasonable Efforts to obtain those rights from such Other Licensee, [***] to Licensee.

(d) OPKO represents that as of the Effective Date, Schedule 6.1(d) lists OPKO's Other Licensees and direct contract manufacturers and suppliers for the Product and, to the best of OPKO's knowledge, all contract manufacturers and suppliers for the Product that are engaged by its direct contract manufacturers and suppliers, all of whom are subject to Sections 6.1(b) and 6.1(c), as applicable. To the extent there is any change to the Other Licensees or contract manufacturers or suppliers for the Product at any time during the Term, OPKO shall promptly inform Licensee by writing, upon which notice Schedule 6.1(d) shall be considered automatically amended to incorporate such change.

6.2 Right of Reference to Regulatory Filings; Third Party Clinical Data.

(a) Each Party shall have the right of cross-reference to the other Party's regulatory filings to the extent necessary to obtain Regulatory Approval for the Product in such Party's respective territory. Subject to Section 7.2(b), if OPKO has the right of cross-reference to an Other Licensee's regulatory filings for the purposes described in the foregoing sentence, then OPKO shall use Commercially Reasonable Efforts to obtain this right from its Other Licensees for the Licensee for its use in the Field and the Licensee Territory.

(b) If [***] is required to [***] in order to obtain the right to cross-reference an Other Licensee's regulatory filings (including, clinical data), then prior to providing Licensee with any, or a right of reference thereto, other than as required by Applicable Law, the Parties shall mutually agree on an [***] or other [***] by Licensee.

6.3 Cooperation.

Each Party shall keep the other Party informed of any material regulatory developments relating to the Product in its own territory through reports at the JSC meetings, or more frequently if the circumstances reasonably require. The Parties shall consult and cooperate in (a) the preparation of each Drug Approval Application for the Product in the Field in the Licensee Territory, and (b) the maintenance of Regulatory Approvals for the Product in the Field in the Licensee Territory; provided, that Licensee shall be primarily responsible for interactions with Regulatory Authorities throughout the Licensee Territory. Licensee shall provide OPKO with reasonable advance notice of any material scheduled meeting with an applicable Regulatory Authority in the Licensee Territory relating to any Drug Approval Application or Regulatory Approval for the Product. Licensee shall duly take OPKO's input into consideration and, if

OPKO desires and permitted by Applicable Law, permit OPKO to participate in any such meeting. Licensee shall promptly (i) provide OPKO with copies of any minutes or other records relating to such meetings with Regulatory Authorities, and (ii) inform OPKO about any significant Regulatory Approval milestones achieved.

6.4 Threatened Regulatory Action.

Each Party shall promptly notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by any Regulatory Authority against itself, its Affiliates or any of its subcontractors, other licensees or sublicensees (including those in the supply and distribution chain of the Product), which may materially and adversely affect development, commercialization or regulatory status of the Product in the other Party's territory (a "**Regulatory Action**"). The Parties shall reasonably and in good faith consult with each other in an effort to determine a mutually acceptable procedure for addressing this Regulatory Action.

6.5 Recalls.

In the event that any Regulatory Authority threatens or initiates any action to remove the Product from the market or there is any recall or equivalent action (whether voluntary or involuntary) in its own territory (a "**Recall**"), each Party shall notify the other Party thereof as soon as practicable. The Parties shall assist each other in gathering and evaluating the relevant information as is necessary of conducting a Recall. Each Party shall, and shall cause its Affiliates, and use reasonable commercial efforts to cause its Other Licensees, subcontractors and sublicensees to, maintain adequate records to permit the Parties to trace the distribution and use of the Products in their respective territories. Unless otherwise agreed by the Parties in a subsequent written agreement, e.g., a quality or similar agreement, Licensee shall have the right to decide whether any Recall with respect to Products in the Field and in the Licensee Territory should be commenced and Licensee shall have the obligation, at its expense to control and coordinate all efforts necessary to conduct such Recall for the Field and in the Territory.

7. **Commercialization**

7.1 Licensee Efforts.

Subject to the terms and conditions of this Agreement, Licensee agrees to use Commercially Reasonable Efforts to (a) launch the Product in the Licensee Territory, on a jurisdiction by jurisdiction basis, as soon as commercially practicable after receipt of Regulatory Approval, and (b) continue diligently thereafter to commercialize, market, promote and sell the Product in the Licensee Territory, in each case for each Initial Indication for which the Product has received Regulatory Approval in the Licensee Territory.

7.2 Promotional Activities.

(a) Upon request of Licensee, OPKO shall deliver to Licensee, [***], a copy of the then existing Marketing Material developed or used by OPKO in connection with the promotion or marketing of the Product in the OPKO Territory. OPKO makes no representation as to the appropriateness or applicability of the Marketing Material in the Licensee Territory. Licensee shall, subject to Applicable Laws, have the right to use and modify all such Marketing Material in connection with its marketing of the Product in the Licensee Territory [***]. Licensee also shall have the right to create, develop and use other Marketing Material in the Licensee Territory at [***]. Licensee shall ensure that any Marketing Material developed or used by Licensee complies with all Applicable Laws in the Licensee Territory. OPKO shall not have any liability with respect to use by or on behalf of Licensee of any Marketing Material provided by OPKO to Licensee under this Section 7.2(a).

(b) Upon request of OPKO, Licensee shall provide to OPKO a copy of any Marketing Material developed by Licensee, including, if requested by OPKO, an English translation thereof, which translation will be provided at [***]. Subject to the terms and conditions of this Agreement, OPKO (and any of its Affiliates and licensees) shall have the right to use in the OPKO Territory and modify such Marketing Material created and developed by Licensee for the Licensee Territory [***]; provided, that OPKO shall be solely responsible for ensuring that such Marketing Material complies with any Applicable Laws in the OPKO Territory, and Licensee shall not have any liability with respect to use by or on behalf of OPKO of any Marketing Material provided by Licensee to OPKO under this Section 7.2(b).

(c) While Licensee shall use all Commercially Reasonable Efforts to [***] for branding the Product (including reasonably considering the use of a trademark consistent with OPKO's trademark for the Product), [***] using the trademarks that [***] from the viewpoint of maximizing the value of the Product in the Licensee Territory. Licensee shall allow the JSC to review the candidate trademarks [***]. Any trademark selected by Licensee (other than those originally owned by OPKO) shall be owned by [***] (“**Licensee Trademark**”) and will be assigned by [***] upon early termination of this Agreement for any reason other than by Licensee in accordance with Section 15.1(c)(ii) or 15.1(c)(iii).

(d) In addition, upon Licensee's request, OPKO shall grant an exclusive license to Licensee to the OPKO Trademark Controlled by OPKO or its Affiliates in the Licensee Territory, which license will continue in perpetuity after the expiration or termination of the Royalty Term, subject to payment and other obligations set forth under this Agreement.

8. Governance

8.1 Joint Steering Committee.

(a) Within [***] days following the date of this Agreement, the Parties shall form a joint steering committee (the “**JSC**”) with responsibility for the overall coordination and

oversight of activities under this Agreement and the Supply Agreement. The JSC shall have the responsibilities and authority allocated to it in this Article 8 and elsewhere in this Agreement, and as otherwise agreed by the Parties.

(b) The JSC shall have representatives from each of OPKO and Licensee. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC shall have a chairperson. The chairperson of the JSC shall be designated by Licensee for the first Agreement Year, shall be designated by OPKO for the second Agreement Year, and shall alternate between the Parties on an annual basis thereafter. The chairperson shall be responsible for calling meetings, and preparing and circulating an agenda in advance of each meeting of the JSC. An OPKO designee shall be responsible for preparing and issuing minutes of each meeting within [***] days thereafter. The minutes of each meeting shall, among other things, record all matters acted upon and approved or disapproved by the JSC, actions to be taken, and any matters the JSC failed to resolve. Such minutes will not be finalized until both Alliance Managers review and confirm in writing the accuracy of such minutes.

(c) Each Party's designees on the JSC shall, collectively, have [***] vote (the "**Party Vote**") on all matters brought before the JSC, which Party Vote shall be determined by consensus of such Party's designees present (in Person or otherwise) at the meeting. Except as expressly provided in this Section 8.1(c), the JSC shall operate as to matters within its jurisdiction by [***] Party Vote. If following such submission, the disagreement is still not resolved, then the disagreement shall be resolved by the Parties as follows:

(i) Any disagreement regarding a submission to a Regulatory Authority that relates to [***], shall be resolved by [***];

(ii) Any disagreement regarding a submission to a Regulatory Authority that relates to [***], shall be resolved by [***];

(iii) Any disagreement regarding material modifications to a submission to a Regulatory Authority other than items (i) and (ii) above that [***], shall be resolved by [***]; and

(iv) Any disagreement regarding any matters related to the OPKO Territory or matters outside the Field in the Licensee Territory, shall be resolved by OPKO.

(d) Each Party will disclose to the other proposed agenda items along with appropriate information at least [***] Business Days in advance of each meeting of the JSC, as applicable; provided, that under exigent circumstances requiring the JSC's input, a Party may provide its agenda items to the other Party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, and such items shall be included in such agenda if such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such JSC meeting.

(e) Notwithstanding the JSC structure established under Section 8.1(a), each Party shall retain the rights, powers and discretion granted to it under this Agreement, and no such rights, powers, or discretion shall be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Without limiting the generality of the foregoing, the JSC shall not have any authority or jurisdiction to amend, modify, or waive compliance with this Agreement, any of which shall require mutual written agreement of the Parties.

8.2 JSC Membership.

Each Party shall appoint an equal number of up to [***] of its senior employees to serve on the JSC. The JSC shall: (a) oversee and coordinate the development of, and the preparation and filing of Drug Approval Applications and other regulatory submissions for, the Products in the Licensee Territory in the Field; (b) oversee the supply of Products for the Licensee Territory in the Field; (c) review material activities to be conducted in connection with commercialization of the Products in the Licensee Territory in the Field; and (d) oversee such other matters as are agreed by the Parties.

8.3 JSC Meetings.

(a) The JSC shall meet at least quarterly unless no later than [***] days in advance of any meeting there is a determination, by agreement of both Parties, that no new business or other activity has transpired since the previous meeting, and that there is no need for a meeting. In such instance, the next meeting will be scheduled. Each Party may also call a special meeting of the JSC in the event such Party reasonably believes that a significant matter must be addressed prior to the next regularly scheduled meeting. The JSC may establish subcommittees, provided that such subcommittees are comprised of equal representation from both Parties and may dissolve them.

(b) The JSC meetings may be via teleconference and/or videoconference.

(c) Each Party shall bear their own expenses in connection with attending meetings of the JSC.

8.4 Alliance Managers.

(a) Each of the Parties shall appoint a single individual to act as that Party's point of contact for day to day communications between the Parties relating to the activities conducted under this Agreement (each, an "**Alliance Manager**"). Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party.

(b) Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within the JSC. Each Alliance Manager will also: (i) be the point of first referral in all matters of conflict resolution; (ii) coordinate the relevant functional representatives of the Parties in developing and executing strategies for the Products in the Licensee Territory in the Field; (iii) provide a single point of communication for seeking consensus both internally within the respective Parties' organizations and between the Parties regarding key strategic issues; (iv) identify and bring disputes to the attention of the JSC in a timely manner; (v) plan and coordinate cooperative efforts and internal and external communications; and (vi) coordinate governance activities, such as the conduct of the JSC meetings and production of meeting minutes so that they occur as set forth in this Agreement, and take actions necessary to facilitate performance of relevant action items resulting from such meetings.

(c) The Alliance Managers shall attend all JSC meetings and support the chairperson of the JSC in the discharge of his/her responsibilities. The Alliance Managers shall be nonvoting participants in the JSC meetings, unless they are also appointed members of the JSC; provided, however, that an Alliance Manager may bring any matter to the attention of the JSC if such Alliance Manager reasonably believes that such matter warrants such attention.

9. Manufacturing, Distribution and Supply

9.1 Manufacture and Supply by OPKO.

Within [***] days following the Effective Date, OPKO and Licensee shall negotiate in good faith the terms of a supply agreement (the "**Supply Agreement**") and related quality agreement (the "**Quality Agreement**") pursuant to which OPKO shall supply to Licensee, directly or through a Third Party, Product in either, at Licensee's option, finished and packaged form ("**Finished Product**"), or unlabeled, bulk capsule form ("**Bulk Product**") to support the development, sale and commercialization of the Product in the Licensee Territory. The Supply Agreement shall provide that the clinical supply of Finished Product, along with placebo, will be supplied to Licensee at [***] and the commercial supply of Finished Product or Bulk Product (at Licensee's option) will be supplied to Licensee at [***], with the understanding that the estimated supply price after the [***] for Finished Product as of the Effective Date is [***] and Bulk Product [***].

9.2 Manufacturing Specific Provisions.

The following terms shall apply to the supply of Bulk Product:

(a) Accreditation. OPKO and the Licensee acknowledge that, pursuant to Applicable Law, the manufacturing sites for the Product and any components thereof, including any test or storage facilities, are required to be accredited as of the time when the Licensee files for Regulatory Approval for the Product in the Licensee Territory. In order to assist Licensee in obtaining Regulatory Approval for the Product in the Licensee Territory, OPKO shall (1) use

good faith efforts to cooperate reasonably with Licensee in applying, or to the extent it has such right causing its contract manufacturers to apply, or (2) permit Licensee to apply on OPKO's behalf for, or to the extent it has such right cause its contract manufacturers to permit Licensee to apply on its behalf, for accreditation to the Regulatory Authorities in the Licensee Territory at least [***] months prior to Licensee's anticipated date for the filing of a New Drug Approval for the Product in the Licensee Territory. In the case of application by the Licensee on behalf of OPKO and/or its contract manufacturers, OPKO shall provide the Licensee with all documents and information available to OPKO and reasonably necessary to support accreditation requested by the Licensee in a timely manner. In the event that OPKO makes changes with respect to the following matters after the accreditation, OPKO shall notify Licensee within [***] days:

- (i) name or address of the Person responsible for the manufacturing establishment;
- (ii) name of the executives responsible for the services;
- (iii) name of the manufacturing establishment;
- (iv) major part of buildings and facilities of the manufacturing establishment; and
- (v) category and (deemed) accreditation number, when a foreign manufacturer obtains additional accreditations for another category, or discontinues operation of their accredited manufacturing establishment.

10. Safety and Surveillance

10.1 Reporting.

Licensee shall be responsible for any reporting of matters regarding the safety of the Product, including Adverse Events, to the appropriate Regulatory Authority in the Licensee Territory, in accordance with Applicable Laws. Licensee shall promptly notify OPKO of any such matter and furnish complete copies of such reports to OPKO in accordance with the Pharmacovigilance Agreement. In the event Licensee or OPKO should become aware of information that may require a Product recall, field alert, withdrawal or field correction arising from any defect in the Product, it shall immediately notify the other Party in writing.

10.2 Adverse Events.

Within [***] days following the Effective Date or as otherwise agreed by the Parties, the Parties shall agree upon the terms of a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"). The Parties shall implement the Pharmacovigilance Agreement and shall provide each other on a regular basis with any appropriate information that enables the other Party to meet its regulatory obligations with respect to the Product or that is relevant to the safe use of the

Product, whether inside or outside the Licensee Territory. The Pharmacovigilance Agreement will be reviewed jointly through a mechanism set forth in the Pharmacovigilance Agreement on an annual basis or when there is a material change in Applicable Laws governing Adverse Event reporting, whether inside or outside the Licensee Territory. OPKO shall maintain the global safety database for the Product, to be set forth in greater detail in the Pharmacovigilance Agreement.

10.3 Medical Inquiries.

Following the Effective Date, Licensee shall be responsible for handling all medical questions or inquiries in the Licensee Territory, including all Product complaints, with regard to any Product sold by or on behalf of Licensee (or any of its Affiliates or Sublicensees) (including having a call center in connection therewith), in each case in accordance with Applicable Laws and this Agreement. OPKO shall immediately forward any and all medical questions or inquiries which it receives with respect to any Product sold by or on behalf of Licensee (or any of its Affiliates or Sublicensees) in the Licensee Territory to Licensee in accordance with all Applicable Laws and Licensee shall immediately forward to OPKO any and all medical questions or inquiries that it receives with respect to Product sold by or on behalf of OPKO in the OPKO Territory or in the Licensee Territory outside the Field, in each case in accordance with all Applicable Laws. OPKO shall be primarily responsible for handling any Product complaints related to quality of the Product if such Product was manufactured by or on behalf of OPKO, and Licensee shall (a) promptly refer all such Product complaints to OPKO, and (b) provide all assistance reasonably requested by OPKO in order to address such Product complaints in the Licensee Territory. Licensee shall be primarily responsible for handling any Product complaints related to quality of the Product if such Product was manufactured by or on behalf of Licensee, and OPKO shall promptly refer all such Product complaints to Licensee. Additional terms shall be included in the Quality Agreement.

10.4 Recall, Withdrawal, or Market Notification of Product.

In the event that any Governmental Authority threatens or initiates any action to remove the Product from the market whether inside the Licensee Territory or inside the OPKO Territory (in whole or in part), the Party receiving notice thereof shall notify the other Party of such communication immediately after receipt thereof. Notwithstanding the foregoing, if a Quality Agreement or Pharmacovigilance Agreement has been executed that applies to any recall, withdrawal or market notification of the Product in the Licensee Territory, then any such recall, withdrawal or market notification shall be conducted as set forth in the applicable agreement.

11. Audit Rights

11.1 Audit Rights.

Licensee shall keep complete and accurate records which are relevant to Product revenues in the Licensee Territory (including gross revenues and Net Sales) and payments under

this Agreement (including milestone payments and Royalty Payments) and such records shall be maintained by Licensee for at least [***] years following their creation. OPKO shall have the right, at OPKO's expense, through an independent certified public accounting firm selected by OPKO that is internationally recognized as one of the four largest accounting firms in the world or like Person reasonably acceptable to Licensee, to examine such records during regular business hours upon reasonable notice during the Term and for [***] years after its expiration or termination to verify the amounts payable to OPKO under Article 4; provided, however, that such examination shall not take place more often than [***] per Agreement Year and shall not cover such records for more than the preceding [***] years. OPKO shall bear the full cost of the audit unless such audit discloses that the deficiency as between the payments made to OPKO during the audited period differs by more than [***] from the amount the accountant determines is correct, and in such case Licensee shall pay to OPKO any outstanding amounts due to OPKO along with the reasonable fees and expenses charged by the accountant within [***] days of such determination. If the audit reveals that Licensee made an overpayment, Licensee may offset the amount of such overpayment against its next scheduled future payment obligations.

12. Intellectual Property

12.1 Ownership of Intellectual Property.

(a) OPKO shall have and retain sole and exclusive right, title and interest in and to any and all OPKO Patents, OPKO Technology, OPKO Trademarks and all other intangible property rights, including, without limitation, any and all inventions, discoveries, writings, trade secrets, methods, practices, procedures, engineering information, designs, devices, improvements, manufacturing information and other technology, including any derivatives of any of the foregoing, whether or not patentable or copyrightable, and any patent applications, patents, or copyrights based therein, thereon and therefrom ("**Inventions**") that are made, discovered, conceived, reduced to practice or generated during the Term by OPKO (or its employees or representatives), solely or with a Third Party, in connection with any activity that is related to the Compound or the Product ("**OPKO Inventions**").

(b) The Parties shall jointly own the right, title and interest in and to all Inventions made, discovered, conceived, reduced to practice or generated during the Term jointly by the Parties (or their respective employees or representatives), with or without a Third Party, in connection with any activity that is related to the Compound or the Product ("**Joint Inventions**").

(c) As between the Parties, Licensee shall own the right, title and interest in and to all Inventions made, discovered, conceived, reduced to practice or generated during the Term solely by Licensee (or its employees or representatives), with or without a Third Party, in connection with any activity that is related to the Compound or the Product ("**Licensee Inventions**").

(d) Notwithstanding any provision of this Agreement to the contrary, the determination of inventorship for Inventions under this Section 12.1 shall be in accordance with U.S. inventorship laws as if such Inventions were conceived or reduced to practice in the U.S.

(e) On a periodic basis during the Term, but no less frequently than [***] per Calendar Quarter, each Party shall disclose to the other Party all OPKO Inventions, Joint Inventions and Licensee Inventions.

12.2 Patent Prosecution.

(a) OPKO shall have [***] responsibility for [***] all of the (i) [***] and (ii) [***] referenced in (i) through (ii), the “**OPKO Prosecution Patents**”). OPKO shall file, prosecute, defend and maintain the OPKO Prosecution Patents described in subsections (i) at its [***], and the Parties shall [***] described in subsection (ii).

(b) Licensee, at its expense, shall have [***] responsibility for filing, prosecuting and maintaining all Licensee Patents (the “**Licensee Prosecution Patents**”).

(c) Each Party shall disclose to the other Party the complete texts of all Patents filed by such Party in the Licensee Territory that relate to the Product. Each Party agrees to comply with all requirements of the applicable patent office in the Licensee Territory to secure the validity and enforceability of Patents related to the Product (e.g., filing working statements) and keep the other Party promptly and fully informed of the course of patent prosecution or other related proceedings and to consider any comments of the other Party in good faith. OPKO shall also have responsibility for filing for any applicable supplementary protection certificates, patent term extensions, pediatric extensions, or their equivalent, if available, in the Licensee Territory with respect to the OPKO Prosecution Patents. Licensee agrees to cooperate with OPKO to secure any such supplementary protection certificates, patent term extensions or their equivalents.

(d) If OPKO wishes to abandon any OPKO Prosecution Patent in the Licensee Territory, then, prior to abandonment, OPKO shall notify Licensee at least [***] days in advance of any statutory bar or other deadline that would result in loss of such OPKO Prosecution Patent. Following such notification, Licensee may, at its option, notify OPKO in writing that it is electing to undertake the filing, prosecution, defense and maintenance of such to-be-abandoned OPKO Prosecution Patent. If Licensee elects to undertake the filing, prosecution, defense and maintenance of such OPKO Prosecution Patent by providing written notice thereof to OPKO, Licensee will be responsible for any direct, out-of-pocket costs relating thereto. If Licensee has undertaken prosecution of an OPKO Patent under this Section 12.2(d), it shall no longer be considered an OPKO Patent under this Agreement for the purpose of the Royalty Term or otherwise.

(e) If Licensee wishes to abandon any Licensee Prosecution Patent, then, prior to abandonment, Licensee shall notify OPKO at least [***] days in advance of any statutory bar

or other deadline that would result in loss of such Licensee Prosecution Patent. Following such notification, OPKO may, at its option, notify Licensee in writing that it is electing to undertake the filing, prosecution, defense and maintenance of such to-be-abandoned Licensee Prosecution Patent. If OPKO elects to undertake the filing, prosecution, defense and maintenance of such Licensee Prosecution Patent by providing written notice thereto to Licensee, OPKO will be responsible for any direct, out-of-pocket costs relating thereto.

12.3 Notification of Patent Litigation.

(a) In the event of the institution of any suit by a Third Party against either Party or their respective Affiliates, licensees or sublicensees in respect of patent infringement involving the manufacture, use, sale, license or marketing of the Product in the Licensee Territory, such Party sued or to whom notice or knowledge of such proceeding shall arise, shall promptly notify the other Party in writing.

(b) If an action, claim, demand, suit, or proceeding (a “**Claim**”) alleging infringement involving the manufacture, use, sale, license or marketing of the Product anywhere in the Licensee Territory is commenced against either Party or their Affiliates, licensees or sublicensees, then the Parties shall promptly meet and agree upon the best strategy to defend against such Claim, with each Party [***]; provided, that OPKO shall have the first opportunity to control the defense of such Claim. If OPKO does not defend a Claim, OPKO shall give Licensee notice thereof within [***] Business Days, and Licensee shall have the sole right to continue such defense [***], except for the [***]. In that case, OPKO shall cooperate with Licensee and provide any documentation or other assistance reasonably requested by Licensee at OPKO’s expense.

12.4 Patent Infringement.

(a) In the event that OPKO or Licensee becomes aware of actual or threatened infringement in the Licensee Territory of an OPKO Prosecution Patent or a Licensee Prosecution Patent, that Party shall promptly notify the other Party in writing.

(i) OPKO shall have the first right to investigate and/or bring an infringement action against any Third Party or defend any action (including oppositions or preliminary injunctions or their equivalent in the Licensee Territory) brought by any Third Party relating to the OPKO Prosecution Patents. If OPKO elects to bring such action, then OPKO shall have full control over the conduct of such action, including the settlement thereof; provided that such settlement does not materially adversely affect Licensee’s rights under this Agreement. Licensee shall reasonably assist OPKO and cooperate in any such action at OPKO’s request, including being joined as a party in such action upon OPKO’s written request.

(ii) The cost of such action shall be [***].

(iii) Any proceeds from such action after the costs of such action have been deducted and reimbursed to OPKO to the extent attributable to lost sales shall be deemed to be and treated as Net Sales under this Agreement and any such proceeds not attributable to lost sales shall be [***].

(b) OPKO shall provide information about its preliminary intention within [***] days after it first learns of any actual or alleged infringement of the OPKO Patents in the Licensee Territory. If OPKO fails to notify the allegedly infringing party with respect to the OPKO Patents and its infringement allegation within [***] days after receiving such information and, thereafter, fails to initiate an enforcement action with respect to such actual infringement within [***] days after receiving credible information and a legal opinion regarding the actual infringement of the OPKO Patents by such Third Party(ies) and the infringing party continues to make, use or sell such infringing product within the Licensee Territory throughout this [***] day period, Licensee shall have the right to enforce the OPKO Patents against such infringers to the extent such infringement relates to the manufacture, use, or sale of products Covered by the OPKO Patents in the Field in the Licensee Territory. Any proceeds from such litigation, to the extent constituting lost sales of Products in the Licensee Territory, shall be deemed to be [***] to OPKO in accordance with Article 4.

(c) In the event that entry of a product to a market segment in which the Product is sold in the Licensee Territory appears imminent and the making, using or selling of that product in the Licensee Territory would infringe any OPKO Patents and such product would be a Competitive Product in the Licensee Territory, OPKO shall take all reasonable actions to determine, within [***] days from the date on which OPKO has legally sufficient basis to believe that such product entry would infringe the OPKO Patents or any longer time period agreed by the Parties, whether OPKO intends to apply promptly and diligently for an interim injunction with regard to such possible product entry and shall promptly inform Licensee of such determination. If OPKO does not take such action, Licensee may take such action.

(d) In any case, the Parties shall reasonably assist each other and cooperate in any such investigation and litigation to ensure there is an aligned global litigation and enforcement strategy.

12.5 Title to Trademarks

The ownership and all goodwill from the use of OPKO Trademarks shall vest in and inure to the benefit of OPKO. The ownership and all goodwill from the use of Licensee Trademarks shall vest in and inure to the benefit of Licensee.

12.6 Trademark License of OPKO Trademark

Upon Licensee's request, OPKO shall grant to Licensee a fully paid-up, exclusive license to use the OPKO Trademarks in the Licensee Territory for the Term in connection with the marketing and promotion of the Product in the Field as contemplated in this Agreement, without

limiting in any way OPKO's rights with respect to the OPKO Trademarks in the OPKO Territory; provided, however, that after expiration of this Agreement, Licensee's license may be exclusive and royalty-bearing pursuant to Section 3.2. OPKO shall use its Commercially Reasonable Efforts to obtain and secure the corresponding domain names in the Licensee Territory that the Parties determine to be appropriate and make such domain names available to Licensee under the conditions of this Section 12.6.

12.7 Maintenance of OPKO Trademarks.

(a) OPKO agrees to use Commercially Reasonable Efforts to register and maintain a registration for the OPKO Trademarks in the Licensee Territory during the Term for use with the Product (including corresponding domain names). Such expenses incurred in connection with the OPKO Trademarks or domain names shall be paid [***]. In the event that any of the OPKO Trademarks are not available for use and registration in connection with the Product in the Licensee Territory due to a rejection of the trademark by a government agency, actual or threatened opposition, cancellation or litigation as to use and/or registration of the OPKO Trademarks by a Third Party, and/or a decision by the JSC that use of the OPKO Trademarks is likely to cause confusion with another's trademark, OPKO shall use Commercially Reasonable Efforts to provide an alternate trademark and shall develop, search, file, register and maintain such alternate trademark at [***].

(b) OPKO shall maintain and monitor the OPKO Trademarks (including the corresponding domain names) and take all reasonable actions to protect the OPKO Trademarks (and the corresponding domain names) from similar Third Party trademarks filed in the Licensee Territory.

(c) OPKO shall maintain and defend all the OPKO Trademarks (and corresponding domain names) as necessary to allow Licensee to fully exercise its rights under Sections 3.2 and 12.6.

12.8 Notification of Trademark Litigation.

In the event of the institution of any suit by a Third Party against OPKO or Licensee for trademark infringement involving the marketing, promotion or sale of the Product in accordance with the annual marketing plan in the Licensee Territory, the Party sued shall promptly notify the other Party in writing. In the event of any infringement of OPKO Trademark, OPKO shall defend such action [***], and [***] from any damages, judgment, costs and expenses (including, reasonable attorneys' fees) arising or resulting therefrom. Licensee shall assist and cooperate with OPKO, [***], to the extent necessary in the defense of such suit. In the event and, as a result of the suit, it becomes necessary to secure or file for a new trademark for the Product, OPKO shall be responsible for searching for and filing for such a mark pursuant to Section 12.7. In the event of any infringement of Licensee Trademark, Licensee shall defend such action [***], and [***] from any damages, judgment, costs and expenses (including, reasonable

attorneys' fees) arising or resulting therefrom. OPKO shall assist and cooperate with Licensee, [***], to the extent necessary in the defense of such suit. In the event and, as a result of the suit, it becomes necessary to secure or file for a new trademark for the Product, Licensee shall be responsible for searching for and filing for such a mark pursuant to Section 12.7.

12.9 Trademark Infringement.

(a) In the event that OPKO or Licensee becomes aware of actual or threatened infringement of a OPKO Trademark anywhere in the Licensee Territory, that Party shall promptly notify the other Party in writing. OPKO shall have the first right, but not the obligation, to investigate and/or bring an infringement and/or opposition or cancellation action against any Third Party. OPKO shall have full control over the conduct of such investigations and litigation, including the settlement thereof. The cost of such investigation and litigation shall be [***]. The Parties shall [***]. Licensee shall reasonably assist OPKO and cooperate in any such investigation and litigation at OPKO's request, including being joined as a party in such action upon OPKO's written request.

(b) OPKO shall provide information about its preliminary intention with respect to any actual or threatened OPKO Trademark within [***] days after it first learns of such actual or alleged infringement. Licensee shall have the right to enforce such OPKO Trademark if OPKO does not initiate an enforcement action within [***] days after it first learns of such infringement. The cost of such litigation brought by Licensee shall be borne by [***].

(c) In the event that OPKO or Licensee becomes aware of actual or threatened infringement of a Licensee Trademark anywhere in the Licensee Territory, that Party shall promptly notify the other Party in writing. Licensee shall have the sole right, but not the obligation, to investigate and/or bring an infringement and/or opposition or cancellation action against any Third Party. Licensee shall have full control over the conduct of such investigations and litigation, including the settlement thereof [***].[***] generated from such litigation.

12.10 Information and Settlements.

OPKO shall keep Licensee informed of the status of any patent or trademark infringement litigation or settlement thereof concerning the Product or the OPKO Trademarks or Patent in the Licensee Territory, provided however that no settlement or consent judgment or other voluntary final disposition of any suit defended or action brought pursuant to this Article 12 shall be entered into without the consent of Licensee if such settlement shall require Licensee to be subject to an injunction or to make a monetary payment or shall otherwise adversely affect Licensee's rights under this Agreement, such consent not to be unreasonably withheld.

12.11 Employees.

Each Party will require all of its and its Affiliates' employees to assign all Inventions that are developed, made or conceived by such employees to the Party or Affiliate according to the

ownership principles described in this Article 12 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Each Party will also require any agents or independent contractors performing an activity pursuant to this Agreement to assign all Inventions that are developed, made or conceived by such agents or independent contractors to such Party according to the ownership principles described in this Article 12 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Each Party will be responsible for any payments required to be made to its employees, agents, independent contractors, or sublicensees in connection with any such assignment.

12.12 Third Party Licenses.

(a) If Third Party Patents are identified by either Party that Cover [***] and the Parties [***] under such identified Third Party patent applications or patents (for patent applications, assuming pending claims therein had issued) for the development, manufacture or commercialization of the Product in the Field in the Licensee Territory to avoid infringement (“**Relevant Patents**”), [***]to obtain a license to such Relevant Patents, [***], in order to permit both Parties to conduct their obligations and exercise their rights under this Agreement; provided, that if [***] the right to do so. The Parties will consult with each other with respect to the negotiation and the final form of such terms and conditions and discuss reasonable terms upon which such Parties [***]; provided, however, that licensor has [***] hereunder in accordance with Section 4.3.

(b) If Third Party Patents are identified by either Party that [***] for the development, manufacture or commercialization of the Product in the Field in the Licensee Territory, but the Parties [***], a license to such [***]; provided, that if [***]. The Parties will consult with each other with respect to the negotiation and the final form of such terms and conditions and discuss reasonable terms upon which such Parties shall share in the cost to obtain the license.

13. **Confidentiality**

13.1 Disclosure of OPKO Technology.

To the extent that OPKO has disclosed or in the future discloses to Licensee any OPKO Technology, Licensee shall not acquire any ownership rights in such OPKO Technology by virtue of this Agreement or otherwise.

13.2 Confidential Information.

OPKO and Licensee shall not use or reveal or disclose to Third Parties any confidential and proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise), including Technology, which is disclosed to it by the other Party or otherwise received or accessed by a Party in the course of performing its

obligations or exercising its rights under this Agreement (“**Confidential Information**”) without first obtaining the written consent of the disclosing Party, except as may be otherwise provided in, or required in order for a Party to fulfill its obligations under, this Agreement. This confidentiality obligation shall not apply to such information that (a) is or becomes a matter of public knowledge (other than by breach of this Agreement by the receiving Party), (b) is required by law to be disclosed, (c) the receiving Party can establish was already known to it or was in its possession at the time of disclosure without obligation of confidentiality, or (d) is disclosed to the receiving Party by a Third Party having the right to do so. The Parties shall take reasonable measures to assure that no unauthorized use or disclosure is made by others to whom access to such information is granted.

Nothing in this Agreement shall be construed as preventing either Party from disclosing any information received from the other Party to an Affiliate of the receiving Party or agent who is necessary for the purposes of enabling the receiving Party to fulfill its obligations under this Agreement; provided, that the receiving Party shall be responsible for breaches of the confidentiality obligations by such Affiliate or agent.

13.3 Public Announcements.

The Parties have agreed upon in principle on the initial press release to announce the execution of this Agreement in substantially the form attached hereto as Schedule 13.3, which shall be finalized upon mutual agreement by the Parties before release. After release of such press releases, no public announcement or other disclosure to Third Parties concerning the existence of or terms of this Agreement shall be made, either directly or indirectly, by either Party, except as may be legally required (including pursuant to stock exchange rules) or as may be required for financial reporting purposes, without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure, *provided* that such Party shall request confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available. A Party seeking additional public announcement shall, to the extent practicable and permitted under Applicable Laws, give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval. A Party commenting on such a proposed public announcement shall provide its comments, if any, within [***] days after receiving the public announcement for review. A Party seeking public announcement shall consider in good faith any comments thereto provided by the other Party and shall comply with the other Party’s reasonable request to remove any and all of such other Party’s Confidential Information from the proposed publication to the extent that such Confidential Information may be removed under Applicable Laws, stock exchange rules or under financial reporting requirements.

14. Restrictive Covenants

14.1 Non-solicitation.

Without the prior written consent of the other Party, each of OPKO and Licensee agrees that during the term of this Agreement and for [***] following termination of this Agreement for any reason, neither it nor any of its Affiliates will directly or indirectly solicit for purposes of hiring any Person employed by the other Party or any of their Affiliates or who was employed by the other Party or any of their Affiliates within the then prior [***], or in any manner seek to induce any such Person to leave his or her employment; provided, however, that this restriction shall not apply to a general advertisement of employment. The foregoing covenant will only apply to Persons employed by the other Party or any of their Affiliates who were actively involved in the activities with respect to the Product contemplated by this Agreement.

14.2 Non-competition.

[***] agrees, on a Product-by-Product basis commencing on [***] and continuing for a [***] period thereafter, that [***] or [***] shall promote, market or sell, or enter into any agreement to promote, market or sell, any [***], in the Licensee Territory in the Field.

15. Termination; Rights And Duties Upon Termination

15.1 Early Termination.

(a) Licensee shall have the right to terminate this Agreement upon [***] days' prior written notice to OPKO for any or no reason.

(b) If (x) OPKO fails to comply with its obligations under Sections 6.1(b)(iii) or 6.1(c), or (y) notwithstanding OPKO's compliance with its obligations under Sections 6.1(b)(iii) or 6.1(c), as applicable, OPKO is not able to obtain the cooperation or agreement of such Third Party with respect to those matters, and the failure or inability to obtain such cooperation or agreement materially and adversely affects Licensee (including without limitation Licensee's ability to obtain Drug Approval Applications), then Licensee shall have the right to terminate this Agreement, upon [***] days' prior written notice if during such [***] period, such Third Party does not comply with OPKO's request to cooperate or provide information, as applicable.

(c) Each Party shall have the right to terminate this Agreement before the end of the Term:

(i) by mutual agreement of the Parties;

(ii) upon a material breach of this Agreement by the other Party where such breach is not cured within [***] days (or [***] days for any payment breach) following the breaching Party's receipt of written notice of such breach from the non-breaching Party; provided, however, that if any breach is not reasonably curable within [***] and if the breaching Party is making a bona fide effort to cure such breach, such termination shall be delayed for a time period to be agreed by both Parties (but in no event more than [***] days) in order to permit

the breaching Party a reasonable period of time to cure such breach; provided, that if Licensee has the right to terminate this Agreement under this Section 15.1(b)(ii), then in lieu of exercising such right of termination, [***], upon delivery of written notice [***], to continue to maintain this Agreement in full force and effect and [***] to Article 20, [***], as applicable, promptly following resolution of such dispute; or

(iii) upon the bankruptcy or insolvency, or the making or seeking to make or arrange an assignment for the benefit of creditors of the other Party, or the initiation of proceedings in voluntary or involuntary bankruptcy, the institution of any reorganization, arrangement or other readjustment of debt plan of the other Party not involving the bankruptcy code, the appointment of a receiver or trustee of such Party's property that is not discharged within [***] days, or any corporate action taken by the board of directors (or similar governing body) of the other Party in furtherance of any of the foregoing actions.

(d) If the breaching Party disputes in good faith that it has materially breached one of its obligations under this Agreement, termination shall not take effect pending resolution of such dispute pursuant to Article 20.

15.2 Continuing Obligations.

In addition to those specifically identified in the Agreement, the following provisions shall survive the termination or expiration of this Agreement for any reason: to the extent applicable, the definitions in Article 1; Article 4 (solely to the extent the payment obligation thereunder accrued prior to the effective date of termination); Articles 11 through 14; this Section 15.2; Sections 15.3 and 15.4; Sections 16.5 through 16.9; and Articles 18 through 20. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement.

15.3 Remedies.

Termination of this Agreement in accordance with its provisions shall not limit the remedies that may be otherwise available to either Party in law or equity.

15.4 Effects of Termination.

(a) Following a termination of this Agreement by Licensee under this Article 15:

(i) subject to Sections 15.4(a)(ii) and 15.4(a)(v) below, all licenses granted to Licensee or its Affiliates under this Agreement shall terminate and all rights in and to the Products in the Licensee Territory shall revert to OPKO;

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. OMISSIONS ARE IDENTIFIED AS []***

(ii) the rights granted by Licensee to OPKO or its affiliates under Section 2.2 shall continue perpetually in accordance with its terms; provided, that if [***] terminates this Agreement in accordance with Section 15.1(c)(ii), then [***] under Section 2.2(a) will become royalty-bearing at the rate of [***] (except that [***] shall be [***]) of products Covered by a Valid Claim of Licensee Patents.

(iii) Licensee shall transfer to OPKO, [***] (unless termination by Licensee was pursuant to Section 15.1(c)(ii) or 15.1(c)(iii), in which case [***]), all relevant and necessary materials, results, analyses, reports, Product data, the URL for Product-specific websites, technology, know-how, regulatory filings, Regulatory Approvals, Licensee Trademarks (in accordance with Section 7.2(c)), and other information in whatever form developed or generated as of the effective date of such termination by or on behalf of Licensee or its Affiliates or Sublicensees with respect to Products;

(iv) Licensee shall submit to any and all Regulatory Authorities in the Licensee Territory in which any regulatory filings have been made or Regulatory Approvals have been granted with respect to the Products, within [***] days after the effective date of such termination, a letter (with a copy to OPKO) notifying such Regulatory Authorities of the transfer of any regulatory filings and Regulatory Approvals for Products in the Licensee Territory from Licensee to OPKO; provided, that [***] shall [***] associated with such transfer if such termination by Licensee is pursuant to Section 15.1(c)(ii) or 15.1(c)(iii);

(v) Licensee, its Affiliates and Sublicensees shall be permitted to sell, subject to the payment of applicable Royalty Payments due under Article 4 and Section 3.2, any Products in inventory (including completion for sale of any work in progress) over the [***] period following termination; and

(vi) any sublicense granted to a Sublicensee that is not in breach under the applicable sublicense or the terms of this Agreement will continue in effect so long as the Sublicensee makes the payments required under Article 5.

(b) Following a termination of this Agreement by OPKO under this Article 15:

(i) all licenses granted to Licensee by OPKO shall terminate; provided, that, unless, [***] to Section 15.1(c)(ii) or Section 15.1(c)(iii), Licensee, its Affiliates and Sublicensees shall be permitted to sell, subject to the payment of applicable Royalty Payments due under Article 4 and Section 3.2, any Products in inventory (including completion for sale of any work in progress) over the [***] period following termination;

(ii) all rights in and to the Products in the Licensee Territory shall revert to OPKO;

(iii) the license granted by Licensee to OPKO under Section 2.2 shall continue perpetually in accordance with its terms;

(iv) Licensee shall transfer to OPKO (which shall be at [***], all relevant and necessary intellectual property rights, materials, results, analyses, reports, Product data, technology, know-how, regulatory filings, Regulatory Approvals and other information in whatever form developed, controlled, or generated as of the effective date of such termination by or on behalf of Licensee or its Affiliates with respect to Products;

(v) Licensee shall submit to any and all Regulatory Authorities in the Licensee Territory, within [***] days after the effective date of such termination, a letter (with a copy to OPKO) notifying such Regulatory Authorities of the transfer of any regulatory filings and Regulatory Approvals for Products in the Licensee Territory from Licensee to OPKO; and

(vi) Any sublicense granted to a Sublicensee that is not in breach under the applicable sublicense or the terms of this Agreement will, at the option of OPKO, continue in effect so long as the Sublicensee makes the payments required under Article 4.

(c) Licensee shall (i) responsibly wind-down, in accordance with accepted pharmaceutical industry and ethical practices, any on-going clinical studies for which it has responsibility hereunder in which patient dosing has commenced and (ii) at OPKO's written election, (A) transfer to OPKO or its designee any ongoing clinical studies to the extent permitted under Applicable Laws and accepted pharmaceutical industry and ethical practices, or (B) if reasonably practicable and not adverse to patient safety, complete such trials.

(d) Nothing in this Article 15 shall limit the Parties' respective rights to damages or specific performance upon the occurrence of an event that constitutes grounds for termination of this Agreement pursuant to Section 15.1 above, as applicable.

16. Representations, Warranties, Covenants, and Indemnification

16.1 Mutual Representations and Warranties.

Each Party hereby represents and warrants (as applicable) to the other Party as of the Effective Date as follows:

(a) It is an entity duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is formed, and has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.

(b) It has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its

obligations hereunder, and this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, except as enforcement may be affected by bankruptcy, insolvency or other similar laws and by general principles of equity.

(c) The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound, or violate any Applicable Laws of any Governmental Authority having jurisdiction over it.

(d) Except with respect to Regulatory Approvals for the development, manufacturing or commercialization of the Product or as otherwise described in this Agreement, all necessary consents, approvals and authorizations of, and all notices to, and filings by such Party with, all Governmental Authorities and other Persons required to be obtained or provided by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the time of execution of this Agreement.

16.2 Representations and Warranties of OPKO.

Except as disclosed on Schedule 16.2(a), OPKO represents and warrants to Licensee that:

(a) it Controls as of the Effective Date the OPKO Patents, OPKO Trademarks and OPKO Technology, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreement, encumbrances, charges or claim of any kind, except to the extent set forth on Schedule 16.2(a);

(b) it has the right to grant Licensee the rights and licenses described in this Agreement;

(c) Appendix A includes a complete and accurate list of all existing OPKO Patents as of the Effective Date;

(d) the OPKO Patents listed on Appendix A that constitute issued patents are in full force and effect and all applicable filing, maintenance and other fees have been timely paid;

(e) the OPKO Patents listed on Appendix A are not the subject as of the Effective Date of any pending re-examination, opposition, interference, inter partes review, litigation or other proceeding;

(f) it has received no written notice of (i) any claim that a Patent or trade secret or other material intellectual property right owned or controlled by a Third Party is or would be infringed or misappropriated by the manufacture, use, sale, offer or sale or import of

the Compounds or Products in the Field, or (ii) any threatened claims or litigation seeking to invalidate or challenge the OPKO Patents or OPKO's rights thereto;

(g) to OPKO's knowledge, no Third Party is infringing the OPKO Patents listed on Appendix A or their counterparts outside the Licensee Territory;

(h) to OPKO's knowledge, there have been no inventorship or ownership challenges with respect to any of the OPKO Patents listed on Appendix A;

(i) to the extent that any of the OPKO Patents listed on Appendix A are pending patent applications as of the Effective Date, those applications are being diligently prosecuted at the Relevant Patent offices;

(j) to OPKO's knowledge, the OPKO Patents and OPKO Technology include all intellectual property rights Controlled by OPKO that (i) are necessary or reasonably useful for the commercialization of the Products by Licensee in the Licensee Territory in the Field in accordance with the terms of this Agreement as contemplated on the Effective Date;

(k) OPKO has prepared, maintained and retained records of the material activities conducted by OPKO and its Affiliates in furtherance of the development of the Compound and the Product and the data resulting therefrom in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and in accordance with Applicable Laws in the OPKO Territory; and

(l) to OPKO's knowledge, OPKO has complied in all respects with and is not in breach, violation or noncompliance of any Applicable Laws with respect to its ownership, use, manufacture or commercialization of the Products.

(m) to OPKO's knowledge, no employee of OPKO or its Affiliates has breached any non-use or confidentiality obligations under any agreement with his or her respective prior employers, or has otherwise misappropriated any trade secret or confidential information of such prior employers, in each case relating to the OPKO Patents and OPKO Technology; and

(n) the Technology that OPKO has disclosed to Licensee constitutes all material Technology in its or its Affiliates' possession regarding the OPKO Technology, the Compounds and Products (including all clinical trial and safety data, databases and analyses).

16.3 OPKO Covenant.

OPKO shall use reasonable efforts to obtain from an Other Licensee the rights to grant the license included under Section 2.1(b) to Licensee; provided, that in no event shall the exercise of reasonable efforts require OPKO to provide monetary or non-monetary consideration for such rights.

16.4 Compliance with Law and Ethical Business Practices.

In addition to the other representations, warranties and covenants made by each Party elsewhere in this Agreement, each Party represents and warrants or covenants and agrees, as applicable, with the other Party that during the Term:

(a) it is licensed, registered, or qualified under all Applicable Laws to do business, and has obtained such licenses, consents, authorizations or completed such registrations or made such notifications as may be necessary or required by Applicable Law to provide any products, goods or services encompassed within this Agreement, and providing such products, goods or services is not inconsistent with any other obligation of such Party;

(b) in conducting its activities and obligations hereunder, such Party will and will cause its Affiliates and, to the extent of its legal right to do so, use reasonable efforts to cause its other representatives to comply in all material respects with all Applicable Laws and accepted pharmaceutical industry business practices, including, to the extent applicable to such Party and each of its Affiliates and other representatives;

(c) to its knowledge with respect to any products, payments or services provided under this Agreement, it has not taken and will not during the Term take any action directly or indirectly to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official or any other Person in order to gain an improper advantage, and has not accepted, and will not accept in the future, such payment;

(d) it complies in all material respects with the laws and regulations of the countries where it operates, including anti-bribery and anti-corruption laws, accounting and record keeping laws, and laws relating to interactions with healthcare professionals or healthcare providers and Government Officials;

(e) to its knowledge, it and each of its Affiliates has been and will, for the Term, be in compliance in all material respects with all applicable global trade laws, including those related to import controls, export controls or economic sanctions, and such Party will cause each of its Affiliates to remain in compliance in all material respects with the same during the Term;

(f) to its knowledge, except to the extent permissible under United States law, neither it nor any of its Affiliates has, on its own behalf or acting on behalf of any other Person, directly or indirectly engaged with, and will not for the Term, directly or indirectly engage in any transactions with, or otherwise deal with, any country or Person targeted by United States, European Union, United Kingdom or other relevant economic sanctions laws in connection with any activities related to such Party's interaction with the other Party, including those contemplated under this Agreement; and

(g) it is, as between the Parties, solely responsible for ensuring the adherence by the Parties and its respective Affiliates in all material respects to all Applicable Laws, in each case with respect to the activities to be conducted under this Agreement.

16.5 Indemnification by OPKO.

OPKO shall defend, indemnify and hold harmless Licensee and its Affiliates and their officers, directors, shareholders, employees, agents, representatives, successors and assigns from and against all claims, complaints, or lawsuits for damages brought by Third Parties (collectively referred to as “**Losses**”) arising out of (a) any negligent act or omission, or willful wrongdoing by OPKO, its Affiliates or representatives in the performance of this Agreement, (b) the failure by OPKO, its Affiliates or representatives to comply with any Applicable Law in the performance of this Agreement, (c) the infringement or misappropriation by OPKO of any patent, copyright, trademark or service mark, as a result of OPKO’s marketing or promotion of the Compound and/or Product which is not pursuant to the terms of this Agreement, (d) any breach of any representation or warranty or covenant or other obligations of OPKO under this Agreement, (e) the sale of the Compound and/or Product in the OPKO Territory or outside the Field in the Licensee Territory by OPKO, its Affiliates or its licensees/sublicensees, and (f) a product liability claim as a result of a defect in the Compound and/or Product supplied by OPKO or its Affiliates, directly or through a Third Party. OPKO shall not be obligated under this Section 16.5 to the extent that Licensee is responsible for indemnifying OPKO for such Losses under Section 16.6.

16.6 Indemnification by Licensee.

Licensee shall defend, indemnify and hold harmless OPKO and its Affiliates and their officers, directors, shareholders, employees, agents, representatives, successors and assigns from and against all Losses arising out of (a) any negligent act or omission, or willful wrongdoing by Licensee, its Affiliates or representatives in the performance of this Agreement, (b) the failure by Licensee, its Affiliates or representatives to comply with any Applicable Law in the performance of this Agreement, (c) the infringement or misappropriation by Licensee of any patent, copyright, trademark, or trade secret, as a result of Licensee’s marketing or promotion of the Product which is not pursuant to the terms of this Agreement or in conformity with the direction of the JSC, (d) any breach of any representation or warranty or covenant or other obligations of Licensee under this Agreement, and (e) the sale of the Product in the Licensee Territory in the Field by Licensee, its Affiliates or its licensees/sublicensees. Licensee shall not be obligated under this Section 16.6 to the extent that OPKO is responsible for indemnifying Licensee for such Losses under Section 16.5.

16.7 Limitations on Indemnification.

The obligations to indemnify, defend, and hold harmless set forth in Sections 16.5 and 16.6 shall be contingent upon the Party seeking indemnification (the “**Indemnitee**”): (a)

notifying the indemnifying Party of a claim, demand or suit within [***] Business Days of receipt of same; provided, however, that Indemnitee's failure or delay in providing such notice shall not relieve the indemnifying Party of its indemnification obligation except to the extent the indemnifying Party is materially prejudiced thereby; (b) allowing the indemnifying Party and/or its insurers the right to assume direction and control of the defense of any such claim, demand or suit; (c) using its Commercially Reasonable Efforts to cooperate with the indemnifying Party and/or its insurers in the defense of such claim, demand or suit; and (d) agreeing not to settle or compromise any claim, demand or suit without prior written authorization of the indemnifying Party. The Indemnitee shall have the right to participate in the defense of any such claim, demand or suit referred to in this Section 16.7 utilizing attorneys of its choice, at its own expense, provided, however, that the indemnifying Party shall have full authority and control to handle any such claim, demand or suit.

16.8 Insurance.

During the Term and for a period of [***] years after the expiration or termination of this Agreement, each Party shall obtain and/or maintain, respectively, at its sole cost and expense, product liability insurance in amounts, respectively, which are reasonable and customary in the pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party. Such product liability insurance shall insure against all liability, including personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of the Product in each Party's respective territory. Each Party shall provide written proof of the existence of such insurance to the other Party upon request.

16.9 Limitation of Liability.

EXCEPT IN THE CASE OF A BREACH OF ARTICLES 13 AND 14, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

17. Assignment

17.1 Assignment.

Neither Party shall assign or transfer its rights or obligations under this Agreement in whole or in part without the prior written consent of the other Party, except to (a) any of its respective Affiliates, or (b) to a Third Party successor or purchaser of all or substantially all of its business or assets to which this Agreement relates, whether in merger, sale of stock, sale of assets or similar transaction. Any attempted assignment in contravention of this Section 17.1 shall be null and void.

18. Notices

18.1 Notices.

Any notice, request, approval or other document required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been given when delivered in Person, or sent by overnight courier service, postage prepaid, or sent by certified or registered mail, return receipt requested, or by email address, to the following email addresses of the Parties and to the attention of the Persons identified below (or to such other address, addresses or Persons as may be specified from time to time in a written notice). Any notices given pursuant to this Agreement shall be deemed to have been given and delivered upon the earlier of (a) if sent by overnight courier service, on the date when received at the address set forth below as proven by a written receipt from the delivery service verifying delivery, (b) if sent by certified or registered mail, three (3) Business Days after mailed by certified or registered mail postage prepaid and properly addressed, with return receipt requested, (c) if sent by email transmission, on the day when sent by email as confirmed by automatic transmission report or the recipient coupled with certified or registered mail or overnight courier service receipt proving delivery, or (d) if delivered in Person, on the date of delivery to the address set forth below as proven by written signature of the recipient.

EirGen Pharma Limited:

EirGen Pharma Limited
Westside Business Park, Old Kilmeaden Road
Waterford, Ireland
Email:
Attention: Damien Burke, CEO

Copy to:

OPKO Health, Inc.
4400 Biscayne Boulevard
Miami, FL 33137, United States of America
Email:
Attention: Steve Rubin

Copy to:

Sidley Austin LLP
2850 Quarry Lake Drive, Suite 301
Baltimore, MD 21209, United States of America
Email:
Attention: Asher M. Rubin

Licensee:

Nicoya Macau Limited
Rooms 503, 504, 5th Floor, Building 7
No. 6, Lane 100, Pingjiaqiao Road
Pudong New Area
Shanghai, CHINA

Copy to:

Greenberg Traurig LLP
One International Place, Suite 2000
Boston, MA 02110, United States of America
Email:
Attention: Fang Xie

19. Miscellaneous

19.1 Force Majeure.

If the performance of any part of this Agreement by either Party, or of any obligation under this Agreement, is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the Party liable to perform, unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use Commercially Reasonable Efforts to avoid or remove such causes of nonperformance and shall continue performance with the utmost dispatch whenever such causes are removed. When such circumstances arise, the Parties shall discuss what, if any modification of the terms of this Agreement may be required in order to arrive at an equitable solution.

19.2 No Partnership or Joint Venture.

It is expressly agreed that OPKO and Licensee shall be independent contractors and that the relationship between the two (2) Parties shall not constitute a partnership, joint venture or agency. Neither OPKO nor Licensee shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so.

19.3 Execution In Counterparts.

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one (1) and the same instrument. Counterparts may be signed and delivered by facsimile or PDF file, with the same effect as if delivered personally.

19.4 Governing Law.

This Agreement shall be deemed to have been made in the Republic of Singapore and its form, execution, validity, construction and effect shall be determined in accordance with the substantive laws of the Republic of Singapore, without regard to conflict of law principals thereof.

19.5 Waiver Of Breach.

The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term in any one (1) or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

19.6 Severability.

In the event any portion of this Agreement were to be held illegal, void or ineffective, the remaining portions of this Agreement shall remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such statute or rule of law. In the event that the terms and conditions of this Agreement are materially altered as a result of this Section 19.6, the Parties shall renegotiate the terms and conditions of this Agreement to resolve any inequities.

19.7 Entire Agreement.

This Agreement, together with the exhibits, attachments, schedules hereto, shall constitute the entire agreement between the Parties relating to the subject matter thereof and shall supersede all previous writings and understandings, except that the relevant Parties shall continue

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. OMISSIONS ARE IDENTIFIED AS []***

to be bound by the confidentiality provisions of that certain Confidentiality Agreement dated June 3, 2020 as may be amended between OPKO Health, Inc. and [***], on behalf of itself and its subsidiaries and Affiliates. No terms or provisions of this Agreement shall be varied or modified by any prior or subsequent statement, conduct or act of either of the Parties, except that the Parties may amend this Agreement by written instruments specifically referring to and executed in the same manner as this Agreement.

19.8 Currency.

Unless otherwise specified in this Agreement, all amounts set forth in this Agreement are in U.S. dollars.

19.9 Form of Payments.

All payments under this Agreement shall be in U.S. dollars in immediately available funds, and, unless instructed otherwise by the receiving Party, shall be made via wire transfer to the account designated from time to time by the receiving Party.

19.10 Good Faith.

Each Party agrees to act reasonably in giving effect to the provisions of this Agreement.

20. Dispute Resolution

20.1 Internal Resolution.

Any dispute, controversy or claim arising out of or relating to a breach or alleged breach of this Agreement, excluding termination (collectively referred to as “**Dispute**”), shall be attempted to be settled by the Parties, in good faith, by submitting each such Dispute to the designated senior management representatives of each Party, who shall meet within [***] Business Days as reasonably requested by either Party to review any Dispute. If the Dispute is not resolved by the designated representatives by mutual agreement within [***] Business Days after a meeting to discuss the Dispute, either Party may at any time thereafter provide the other Party written notice specifying the terms of such Dispute in reasonable detail. Within [***] Business Days of receipt of such notice, the chief executive officer (or other senior executive with authority to resolve the dispute) of each Party shall meet at a mutually agreed upon time and location for the purpose of resolving such Dispute. They will discuss the problems and/or negotiate for a period of up to [***] days in an effort to resolve the Dispute or negotiate an acceptable interpretation or revision of the applicable portion of this Agreement mutually agreeable to both Parties, without the necessity of formal procedures relating thereto.

20.2 Arbitration.

Any controversy or claim arising out of or relating to this Agreement (other than any matter subject to a Party's final decision-making authority as described in Section 8.1(c)) shall be settled by arbitration in accordance with the rules of the Singapore International Arbitration Centre. The arbitration shall be conducted in English. The seat of the arbitration shall be in Singapore. In any arbitration pursuant to this Agreement, the award or decision shall be rendered by a majority of the members of an arbitration panel consisting of three (3) independent arbitrators. Each Party shall appoint one (1) arbitrator, and the third arbitrator shall be selected jointly by the two arbitrators appointed by the Parties, unless the Parties otherwise agree as to the identity of the third arbitrator. If the two arbitrators appointed by the Parties are unable to agree upon the third arbitrator within [***] days of any request for arbitration, such arbitrator shall be selected by the AAA. Persons selected to serve as an arbitrator need not be a professional arbitrator, and Persons such as lawyers, accountants, brokers and bankers shall be acceptable. Before undertaking to resolve the dispute, the arbitrators shall be duly sworn faithfully and fairly to hear and examine the matters in controversy and to make a just award according to the best of his or her understanding. The written decision of the arbitrators shall be final, conclusive and binding on the Parties. Each Party shall bear its own costs and expenses (including legal fees and expenses) relating to the arbitration proceeding, except that the fees of the arbitrators and other related costs of the arbitration shall be shared equally by the Parties. The arbitrators shall be required, in granting any relief, to comply with any express provisions of this Agreement relating to damages or the limitation thereof. Judgment upon the award may be entered by any court having jurisdiction thereof or having jurisdiction over the relevant Party or its assets. Either Party has the right to apply to courts having jurisdiction over controversies or claims arising out of this Agreement for interim relief necessary to preserve the Party's rights, including pre-arbitration attachments or injunctions, until the arbitral tribunal is constituted. After the constitution of the arbitral tribunal, the arbitrators shall have exclusive jurisdiction to consider applications for interim relief.

21. **Performance**

21.1 Performance.

To the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its requisite efforts (which may be Commercially Reasonable Efforts) to perform any such affected obligations as required by this Agreement.

[Signatures on following page]

CERTAIN IDENTIFIED INFORMATION HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. OMISSIONS ARE IDENTIFIED AS [*]**

NOW, THEREFORE, the Parties, through their authorized officers, have executed this Agreement as of the date first written above.

EIRGEN PHARMA LIMITED
By: /s/ Damien Burke
Name: Damien Burke
Title: CEO

NICOYA Macau Limited
By: /s/ Gan Ding
Name: Gan Ding
Title: Chief Executive Officer

EXCLUSIVE LICENSE AGREEMENT

by and between

OPKO Health, Inc.

and

**CAMP4 Therapeutics Corporation
entered into as of**

July 6, 2021

TABLE OF CONTENTS

	<u>Page</u>
ARTICLE 1 DEFINITIONS	1
ARTICLE 2 LICENSES	11
2.1 Licenses	11
2.2 New Applications	11
2.3 Non-Compete	12
ARTICLE 3 LICENSED PRODUCT DEVELOPMENT	12
3.1 Overview	12
3.2 Development Diligence and Responsibilities	12
3.3 Technology Exchange and Use	12
3.4 Development	13
ARTICLE 4 MANUFACTURING AND SUPPLY	13
4.1 Manufacturing	13
ARTICLE 5 REGULATORY MATTERS	13
5.1 Regulatory Responsibilities	13
5.2 Cooperation	13
5.3 Notification of Threatened Action	13
ARTICLE 6 COMMERCIALIZATION	14
6.1 Commercialization Diligence	14
6.2 Responsibility for Commercialization in the Territory	14
6.3 Commercialization Updates	14
ARTICLE 7 COMPENSATION	14
7.1 Upfront Consideration	14
7.2 Equity Consideration	14
7.3 Annual License Fee	14
7.4 Milestone Payments	15
7.5 Royalty Payments	16
7.6 Royalty Payment Adjustments	16
7.7 Upfront Payment Share	17
7.8 Foreign Exchange	17
7.9 Payment Method; Late Payments	17
7.10 Records	18
7.11 Audits	18
7.12 Taxes	18
7.13 No Joint Venture	19
ARTICLE 8 INTELLECTUAL PROPERTY MATTERS	19
8.1 Ownership of Existing Know-How and Patent Rights	19
8.2 Ownership of Sole Inventions	19
8.3 Inventorship	19
8.4 Prosecution of Patent Rights	19
8.5 Patent Right and Know-How Enforcement in the Territory	20
8.6 Third Party Claim	21
8.7 Trademarks	21
ARTICLE 9 REPRESENTATIONS AND WARRANTIES; COVENANTS	21
9.1 Mutual Representations and Warranties	21
9.2 Additional Representations and Warranties of CAMP4	22
9.3 Additional Representations and Warranties of OPKO	22
9.4 Covenants	24
9.5 No Other Representations or Warranties	25
ARTICLE 10 INDEMNIFICATION	25
10.1 Indemnification by OPKO	25
10.2 Indemnification by CAMP4	25
10.3 Indemnification Procedures	25
10.4 Limitation of Liability	26
10.5 Insurance	26

ARTICLE 11 CONFIDENTIALITY 26

- 11.1 Confidentiality 26
- 11.2 Secrecy of OPKO Know-How 27
- 11.3 Residual Knowledge 27
- 11.4 Technical Publication 27
- 11.5 Publicity; Terms of Agreement 27
- 11.6 Prior Confidentiality Agreements 28
- 11.7 Unauthorized Use 28

ARTICLE 12 TERM AND TERMINATION 28

- 12.1 Term 28
- 12.2 Termination for Convenience by CAMP4 28
- 12.3 Termination for Breach 28
- 12.4 Effect of Expiration or Termination 29
- 12.5 Rights in Bankruptcy 30
- 12.6 Survival 31

ARTICLE 13 DISPUTE RESOLUTION 32

- 13.1 Referral of Disputes to Parties Executive Officers 32
- 13.2 Litigation 32
- 13.3 Equitable Relief 32
- 13.4 Governing Law 32
- 13.5 Waiver of Jury Trial 32
- 13.6 Patent Right and Trademark Disputes 32

ARTICLE 14 MISCELLANEOUS 33

- 14.1 Entire Agreement; Amendment 33
- 14.2 Force Majeure 33
- 14.3 Notices 33
- 14.4 No Strict Construction; Interpretation; Headings 34
- 14.5 Assignment 34
- 14.6 Performance by Affiliates 34
- 14.7 Further Assurances and Actions 34
- 14.8 No Third Party Beneficiaries 34
- 14.9 Severability 35
- 14.10 No Waiver 35
- 14.11 Relationship of the Parties 35
- 14.12 English Language 35
- 14.13 Expenses 35
- 14.14 Acknowledgments and Representations 35
- 14.15 Counterparts 35

Exhibits and Schedules

- Schedule 1.54 Licensed Compounds
- Schedule 1.66 OPKO Patent Rights
- Schedule 3.3 Technology Transfer Plan
- Schedule 7.2 Form of Subscription Agreement
- Schedule 9.3 OPKO Disclosures

EXCLUSIVE LICENSE AGREEMENT

This **Exclusive License Agreement** (this “**Agreement**”) is entered into as of June 30, 2021 (the “**Effective Date**”) by and among **OPKO Health, Inc.**, a company organized under the laws of Delaware, having a place of business at 4400 Biscayne Blvd. Miami, FL 33137 (“**OPKO**”), and **CAMP4 Therapeutics Corporation**, a corporation organized under the laws of Delaware, having a place of business at One Kendall Square Building 1400 West, 3rd Floor, Cambridge, MA 02139 (“**CAMP4**”). **OPKO** and **CAMP4** are sometimes referred to individually as a “**Party**” and collectively as the “**Parties**.” Except as otherwise indicated, capitalized terms used herein will have the meanings set forth in ARTICLE 1.

RECITALS

Whereas, **OPKO** owns or Controls the **OPKO Technology**, and has the right to Exploit the Licensed Products in the Territory; and

Whereas, **CAMP4** desires to obtain from **OPKO**, and **OPKO** desires to grant to **CAMP4**, certain licenses to Exploit the Licensed Compounds and Licensed Products in the Field in the Territory pursuant to the terms and conditions set forth in this Agreement.

Now, Therefore, the Parties hereby agree as follows:

ARTICLE 1 DEFINITIONS

“**Affiliate**” means, with respect to either Party, any Person that directly or indirectly through one or more intermediaries controls, is controlled by or is under common control with such Party, for so long as such control exists; for purposes of this definition, “control” (including, with correlative meaning, the terms “controlled by” or “under common control with”) means (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than 50% of the voting securities or other ownership interest of a Person (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

“**Amount**” has the meaning set forth in Section 7.12(b) (Tax Withholding).

“**AOP**” has the meaning set forth in Section 14.11 (Relationship of the Parties).

“**Bankruptcy Code**” means, as applicable, the U.S. Bankruptcy Code (in the United States of America), as amended from time to time, and the rules and regulations and guidelines promulgated thereunder, or any applicable bankruptcy laws of any other country or competent Governmental Authority, as amended from time to time, and the rules and regulations and guidelines promulgated thereunder.

“**Breaching Party**” has the meaning set forth in Section 12.3 (Termination for Breach).

“**Business Day**” means any day other than a day on which the commercial banks in Boston, Massachusetts or Miami, Florida are authorized or required to be closed.

“**Calendar Quarter**” means each successive period of three calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term commences on the Effective Date and ends

on the day immediately before the first to occur of January 1, April 1, July 1, or October 1 after the Effective Date, and the last Calendar Quarter ends on the last day of the Term.

“**Calendar Year**” means each successive period of 12 calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term commences on the Effective Date and ends on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term commences on January 1 of the year in which the Term ends and ends on the last day of the Term.

“**CAMP4**” has the meaning set forth in the preamble hereto.

“**CAMP4 Indemnitees**” has the meaning set forth in Section 10.1 (Indemnification by OPKO).

“**Change of Control**” means, with respect to either Party, (a) a merger, consolidation, share exchange or other similar transaction involving such Party and any Third Party which results in the holders of the outstanding voting securities of such Party, or any Affiliate that controls such Party directly or indirectly, immediately before such merger, consolidation, share exchange or other similar transaction, ceasing to hold more than 50% of the combined voting power of the surviving or continuing entity or the ultimate parent entity of such surviving or continuing entity immediately after such merger, consolidation, share exchange or other similar transaction, (b) the acquisition by a Third Party, or a group of Third Parties acting in concert, of more than 50% of the outstanding voting equity securities of such Party or any Affiliate that controls such Party directly or indirectly immediately before such acquisition other than pursuant to a *bona fide* financing transaction, or (c) the sale, exclusive license, or other transfer to a Third Party of all or substantially all of such Party’s assets or business or all of such Party’s assets or business to which this Agreement relates. For the purpose of this definition of “Change of Control,” (i) the term “group” includes any group acting for the purpose of acquiring, holding, or disposing of securities within the meaning of the relevant laws of the jurisdiction of the relevant Party (e.g., with respect to the U.S., Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and Rule 13d-5(b)(1) under said Act, as amended) and (ii) the foregoing clauses do not include any sale or transfer solely to an Affiliate of the applicable Party.

“**Claims**” has the meaning set forth in Section 10.1 (Indemnification by CAMP4).

“**Clinical Trial**” means any study conducted in humans (healthy volunteers or patients) according to a set protocol and meeting the requirements of GCP.

“**CMC**” means the chemistry, Manufacturing, and controls of Licensed Product.

“**Combination Product**” means a Royalty Bearing Product that is (a) sold in the form of a combination that contains a Licensed Compound together with one or more other therapeutically active pharmaceutical agents (whether coformulated or copackaged or otherwise sold for a single price), (b) sold for a single invoice price together with any (i) delivery device or component therefor, (ii) companion diagnostic related to any Licensed Compound, or (iii) process, service, or therapy other than a Licensed Compound (such additional therapeutically active pharmaceutical agent and each of (i) – (iii), an “**Other Component**”), or (c) defined as a “combination product” by the FDA pursuant to 21 C.F.R. §3.2(e) or its foreign equivalent.

“**Commercialization**,” “**Commercialize**,” or “**Commercializing**” means, with respect to any product, any and all activities directed to marketing, advertising, promoting, distributing, importing, exporting, using, offering to sell, and selling or otherwise commercializing such product, including: pre-launch activities to prepare a market for potential sales; modeling and pharmaco-economic studies, epidemiological studies; government affairs, and public policy activities; patient services, patient advocacy engagement; and activities related to pricing and reimbursement,

including seeking and maintaining any required pricing and reimbursement approvals; but excluding, in each case, any activities directed to Manufacturing or Development. “**Commercialized**” will be construed accordingly.

“**Commercially Reasonable Efforts**” means, with respect to CAMP4’s obligations or tasks under this Agreement, the performance of such obligations or tasks undertaken in good faith, using a level of effort consistent with the level of effort that [***] as a Licensed Product at a [***], taking into account [***] (including likelihood and duration thereof), [***] (taking into account [***] under this Agreement), and all other relevant factors. Commercially Reasonable Efforts will be determined on a country-by-country basis for the applicable Licensed Product, and it is anticipated that the level of effort will change over time, reflecting changes in the status of such Licensed Product and the market or country involved. OPKO expressly understands and accepts that [***], and that [***]. With respect to any efforts to Commercialize a Licensed Product, CAMP4 agrees that it would not have made Commercially Reasonable Efforts to Commercialize a Licensed Product if it reduced its efforts deliberately to avoid or postpone reaching any milestone payment set forth herein set forth in.

“**Companion Diagnostic**” means a diagnostic product or method used in combination with a Licensed Compound or Licensed Product and in connection with a specific patient or group of patients.

[***] has the meaning set forth in Section 2.3.

“**Competitive Infringement**” has the meaning set forth in Section 8.5(b).

“**Competitive Product**” means any pharmaceutical product that is (a) intended for the prevention or treatment of Dravet syndrome for which the [***] or (b) intended for the prevention or treatment of a non-Dravet indication or use for which the [***]; provided that any [***].

“**Confidential Information**” means (a) with respect to each Party, all Know-How or other information, including proprietary information and materials (whether or not patentable) regarding or embodying such Party’s technology, products, business information or objectives, that is communicated by or on behalf of the disclosing Party to the receiving Party or its permitted recipients, including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement; provided that, all such information that solely relates to any Licensed Compound or Licensed Product shall be deemed the Confidential Information of CAMP4, regardless of which Party is the disclosing Party of such information, and (b) the terms of this Agreement, for which both Parties shall be deemed to be the receiving Party; *provided* that Confidential Information will not include information that:

- (a) is published by a Third Party or otherwise is or hereafter becomes part of the public domain by public use, publication, general knowledge, or the like through no breach of this Agreement on the part of the receiving Party;
- (b) is in the receiving Party’s possession prior to disclosure by the disclosing Party hereunder, and not through a prior disclosure by the disclosing Party, without any obligation of confidentiality with respect to such information;
- (c) is subsequently received by the receiving Party from a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party under any agreement between such Third Party and the disclosing Party; or
- (d) is independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party’s Confidential Information.

“**Contingent Shares**” has the meaning set forth in Section 7.2 (Equity Consideration).

“**Control**” or “**Controlled**” means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any tangible Know-How, the legal authority or right to physical possession of such tangible Know-How, with the right to provide such tangible Know-How to the other Party on the terms set forth herein, or (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Materials, intangible Know-How, or other intellectual property, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Materials, intangible Know-How, or other intellectual property on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, licenses, or sublicense.

“**Cover(ed)**” means, when used to refer to the relationship between a particular Patent Right and particular subject matter, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in, or is otherwise claimed by, such Patent Right.

“**Default Notice**” has the meaning set forth in Section 12.3(a) (Notice).

“**Develop**” or “**Development**” means, with respect to any product, any and all activities that relate to obtaining, maintaining or expanding Regulatory Approval of such product, including any and all activities related to the design, research, discovery, generation, identification, profiling, characterization, preclinical development, or nonclinical studies of such product, CMC activities, clinical drug development activities conducted before or after obtaining Regulatory Approval for such product that are reasonably related to or leading to the development, preparation, or submission of data and information to a Regulatory Authority for the purpose of obtaining, supporting, expanding or maintaining Regulatory Approval of such product, together with all activities related to pharmacokinetic profiling, design and conduct of Clinical Trials of such product, pharmacovigilance activities, adverse event reporting, and regulatory affairs, statistical analysis, report writing and the creation and submission of Regulatory Materials related to the foregoing (including the services of outside advisors and consultants in connection therewith); but excluding, in each case, any activities directed to Commercialization or Manufacturing. “**Developing**” and “**Developed**” will be construed accordingly.

“**Development Milestone Event**” has the meaning set forth in Section 7.4(a) (Development Milestone Payments).

“**Development Milestone Payment**” has the meaning set forth in Section 7.4(a) (Development Milestone Payments).

“**Dispute**” has the meaning set forth in Section 13.1 (Referral of Disputes to Parties Executive Officers).

“**Dollars**” or “**\$**” means U.S. dollars.

“**Dravet Product**” means any Licensed Product comprising or containing OPK88001.

“**Effective Date**” has the meaning set forth in the preamble hereto.

“**EMA**” means the European Medicines Agency or any successor entity.

“**Equity Consideration**” has the meaning set forth in Section 7.2 (Equity Consideration).

“**Exclusive Field**” means all human pharmaceutical, prophylactic, and therapeutic uses.

“**Executive Officers**” has the meaning set forth in Section 12.3(b) (Process for Disputes).

“**Exploit**” means to make, have made, import, export, distribute, use, have used, sell, have sold, or offer for sale, Develop, Manufacture, Commercialize, register, modify, enhance, improve, or otherwise exploit. “**Exploitation**” and “**Exploiting**” will be construed accordingly.

“**FD&C Act**” means the U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

“**FDA**” means the U.S. Food and Drug Administration or any successor entity.

“**Field**” means the Exclusive Field and the Non-Exclusive Field.

“**First Commercial Sale**” means, with respect to a Royalty Bearing Product and a country in the Territory, the first sale of such Royalty Bearing Product by CAMP4 or its Affiliate or Sublicensee for monetary value to a Third Party in such country after receipt of Regulatory Approval for such Royalty Bearing Product has been obtained in such country and where the sale results in a recordable Net Sale. First Commercial Sale excludes transfers of Royalty Bearing Product to Third Parties as *bona fide* samples, as donations, for the performance of Clinical Trials, or for any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program.

“**GAAP**” means U.S. generally accepted accounting principles.

“**Generic Product**” means, with respect to a Royalty Bearing Product, any pharmaceutical product that (a) is an AB rated generic equivalent of the Royalty Bearing Product, (b) is approved by the Regulatory Authority in the Field in reliance, in whole or in part, on a prior Regulatory Approval of such Royalty Bearing Product, or (c) contains the same active ingredient as the applicable Royalty Bearing Product, including any fixed-dose combination Royalty Bearing Product and in the same dosage form as the applicable Royalty Bearing Product.

“**Governmental Authority**” means any multi-national, federal, state, local, municipal, provincial, or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court, arbiter, or other tribunal).

“**ICH**” means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

[***]

“**IND**” means any Investigational New Drug application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations or a similar application or submission for a product filed with a Regulatory Authority in a country or group of countries, including a CTA filed with the EMA.

“**Indemnified Party**” has the meaning set forth in Section 10.3 (Indemnification Procedures).

“**Indemnifying Party**” has the meaning set forth in Section 10.3 (Indemnification Procedures).

“**Initial Shares**” has the meaning set forth in Section 7.2 (Equity Consideration).

“**Initiation**” means the first dosing of a third patient in a Clinical Trial.

“**Know-How**” means any (a) proprietary information or materials, including records, improvements, modifications, techniques, assays, processes, methods, utilities, formulations, compositions of matter, articles of manufacture, materials (including chemical or biological materials), creation, discovery or finding, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, marketing, pricing and distribution costs, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how, and trade secrets (in each case, whether or not patentable, copyrightable, or otherwise protectable), and (b) any physical embodiments of any of the foregoing.

“**Laws**” means all laws, statutes, rules, codes, regulations, orders, decrees, judgments or ordinances of any Governmental Authority, or any license, permit or similar right granted under any of the foregoing, or any similar provision having the force or effect of law.

“**Licensed Compounds**” means all oligonucleotides, including OPK88001, together with any derivative or modification thereof [***]. The Licensed Compounds existing as of the Effective Date are set forth in Schedule 1.54 (Licensed Compounds) hereto.

“**Licensed Product**” means any pharmaceutical product comprising or containing a Licensed Compound, alone or in combination with one or more other active ingredients, in any and all forms, in current and future formulations, dosage forms and strengths, and delivery modes. All Licensed Products comprising or containing the same Licensed Compound will be considered the same Licensed Product under this Agreement.

“**Manufacturing**” or “**Manufacture**” means, with respect to any product (including active pharmaceutical ingredient and other material contained therein), any and all activities related to the manufacture of such product, including qualification, validation and scale-up, pre-clinical, clinical and commercial manufacture, packaging, labeling, filling, finishing, assembly, processing, in-process and finished product testing, release of such product or any component or ingredient thereof, quality assurance, quality control and audit activities related to manufacturing, testing and release of such product, ongoing stability tests, storage, shipping, supply or storage of such product (or any components or process steps involving such product or any companion diagnostic), placebo or comparator agent, as the case may be, product characterization, technical support activities, and regulatory activities related to any of the foregoing, but excluding any activities directed to Development or Commercialization of such product.

“**Net Sales**” means, with respect to any Royalty Bearing Product, the gross amount invoiced for Royalty Bearing Products sold by CAMP4 or its Affiliates or Sublicensees to Third Parties, less the following deductions, to the extent actually taken, from such gross amounts:

- (a) credits, price adjustments, or allowances for damaged products, and returns or rejections of such Royalty Bearing Product;
- (b) trade, cash, and quantity discounts, allowances and credits (other than price discounts granted at the time of invoicing that have already been included in the gross amount invoiced);
- (c) chargeback payments and rebates (or the equivalent thereof), retroactive or otherwise, granted to group purchasing organizations, managed health care organizations, health maintenance

organizations, any other providers of health insurance coverage or to federal, state/provincial, local and other governments, including their agencies, or to trade customers;

- (d) any invoiced freight, postage, shipping, insurance, and other transportation charges, as well as any fees for services provided by wholesalers and warehousing chains related to the distribution of such Royalty Bearing Product;
- (e) sales, value-added (to the extent not refundable in accordance with applicable Law), and excise taxes, tariffs, and duties, and other taxes directly related to the sale (but not including taxes assessed against the income derived from such sale);
- (f) the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers, or Medicare Prescription Drug Plans relating to such Royalty Bearing Product;
- (g) any invoiced amounts from a prior period that are not collected and are written off by CAMP4 or its Affiliates, including bad debts, which amounts shall be capped at [***] of Net Sales in a particular country in each Calendar Year;
- (h) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) and reasonably allocable to sales of the Royalty Bearing Products; and
- (i) any other similar and customary deductions that are consistent with GAAP.

For purposes of calculating Net Sales, all Net Sales will be converted into Dollars in accordance with Section 7.8 (Foreign Exchange).

For this definition:

- (A) the transfer of Royalty Bearing Product by or among CAMP4, its Affiliates or Sublicensees is not considered a sale unless any such Affiliate or Sublicensee is the end user of such Royalty Bearing Product; and
- (B) Net Sales will not include dispositions transfers of Royalty Bearing Product to Third Parties *as bona fide* samples, as donations, for the performance of Clinical Trials, or for any expanded access program, any compassionate sales or use program (including named patient program or single patient program), or any indigent program.

If, with respect to a Combination Product, CAMP4 or its Affiliate or Sublicensee separately sells in such country or other jurisdiction, (A) a product containing as its sole active ingredient a Licensed Compound contained in such Combination Product (the “**Mono Product**”) and (B) products containing Other Components (which Other Components must show synergistic benefit to OPK88001) in such Combination Product, then the Net Sales attributable to such Combination Product will be calculated by multiplying actual Net Sales of such Combination Product by the fraction $A/(A+B)$ where: “A” is CAMP4’s (or its Affiliate’s or Sublicensee’s, as applicable) average Net Sales price during the period to which the Net Sales calculation applies for the Mono Product in such country or other jurisdiction and “B” is CAMP4’s (or its Affiliate’s or Sublicensee’s, as applicable) average Net Sales price during the period to which the Net Sales calculation applies in such country or other jurisdiction, for the Other Components in such Combination Product.

If, with respect to a Combination Product, CAMP4 or its Affiliate or Sublicensee separately sells in such country or other jurisdiction the Mono Product, but does not separately sell in such country or other jurisdiction the Other Components in such Combination Product, then the Net Sales attributable to such Combination Product will be calculated by multiplying the Net Sales of such Combination Product by the fraction A/C where: “A” is CAMP4’s (or its Affiliate’s or Sublicensee’s, as applicable) average Net Sales price during the period to which the Net Sales calculation applies for the Mono Product in such country or other jurisdiction, and “C” is CAMP4’s (or its Affiliate’s or Sublicensee’s, as applicable) average Net Sales price in such country or other jurisdiction during the period to which the Net Sales calculation applies for such Combination Product.

If, with respect to a Combination Product, CAMP4 and its Affiliates and Sublicensees do not separately sell in such country or other jurisdiction the Mono Product, but do separately sell the Other Components contained in such Combination Product, then the Net Sales attributable to such Combination Product will be calculated by multiplying the Net Sales of such Combination Product by the fraction $(C-B)/C$ where: “C” is CAMP4’s (or its Affiliate’s or Sublicensee’s, as applicable) average Net Sales price in such country or other jurisdiction during the period to which the Net Sales calculation applies for such Combination Product and “B” is CAMP4’s (or its Affiliate’s or Sublicensee’s, as applicable) average Net Sales price during the period to which the Net Sales calculation applies in such country or other jurisdiction for the Other Components in such Combination Product.

If, with respect to a Combination Product, CAMP4 and its Affiliates and Sublicensees do not separately sell in such country or other jurisdiction any of the Mono Product or the Other Components in such Combination Product, then the Net Sales attributable to such Combination Product will be determined by CAMP4 in good faith based on the relative fair market value of such Mono Product and such Other Components.

“**New Application**” has the meaning set forth in Section 2.2(a) (New Applications).

“**Non-Breaching Party**” has the meaning set forth in Section 12.3 (Termination for Breach).

“**Non-Dravet Product**” means any Licensed Product other than a Dravet Product or an [***].

“**Non-Exclusive Field**” means [***].

“**OPK88001**” means the molecule Developed by OPKO for the treatment of Dravet syndrome and further described on Schedule 1.54 (Licensed Compounds) hereto.

“**OPKO**” has the meaning set forth in the preamble hereto.

“**OPKO Indemnitees**” has the meaning set forth in Section 10.2 (Indemnification by CAMP4).

“**OPKO Know-How**” means all Know-How owned or Controlled by OPKO or any of its Affiliates on the Effective Date or at any time during the Term, in each case, that is necessary or reasonably useful to Exploit the Licensed Compounds or any Licensed Product in the Territory in the Field. Notwithstanding the foregoing, OPKO Know-How excludes any Know-How owned or Controlled by OPKO or any of its Affiliates on the Effective Date or at any time during the Term that specifically relates to any diagnostic product Exploited or intended to be Exploited by OPKO or any of its Affiliates in the Non-Exclusive Field during the Term.

“**OPKO Patent Right**” means any Patent Right owned or Controlled by OPKO or any of its Affiliates on the Effective Date or at any time during the Term that is necessary or reasonably useful to [***]. The OPKO Patent Rights existing as of the Effective Date are set forth in Schedule 1.66 (OPKO Patent Rights) hereto (provided that, [***]). Notwithstanding the foregoing, OPKO Patent Rights exclude [***].

“**OPKO Technology**” means OPKO’s interest in the OPKO Patent Rights and OPKO Know-How.

“**Other Component**” has the meaning set forth in Section 1.15 (Combination Product).

[***]

“**Other Products**” means any [***] or Non-Dravet Product.

“**Owned Patent Rights**” has the meaning set forth in Section 9.3(a) (OPKO Patent Rights Title; Encumbrances).

“**Patent Rights**” means any and all (a) patents, (b) patent applications, including all provisional and non-provisional applications, patent cooperation treaty (PCT) applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patent rights granted thereon, (c) all patents-of-addition, reissues, re-examinations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates, patent term extensions, and equivalents thereof, (d) inventor’s certificates, letters patent, or (e) any other substantially equivalent form of government issued right substantially similar to any of the foregoing described in subsections (a) through (e) above, anywhere in the world.

“**Person**” means an individual, a corporation, a partnership, an association, a trust, or other entity or organization, including a Governmental Authority.

“**Phase 1 Clinical Trial**” means a Clinical Trial of a product in human subjects that provides for the first introduction into humans of a product and that is conducted in healthy volunteers or patients to obtain information on product safety, tolerability, pharmacological activity or pharmacokinetics, or a similar clinical study prescribed by the Regulatory Authorities, from time to time, pursuant to applicable Law or otherwise and that satisfies the requirements set forth in 21 C.F.R. § 312.21(a) (or the non-U.S. equivalent thereof).

“**Prior CDA**” has the meaning set forth in Section 11.6 (Prior Confidentiality Agreements).

“**Product Trademarks**” means the Trademark(s) to be used by CAMP4 or its Affiliates or its or their respective Sublicensees or by OPKO or its Affiliates or permitted sublicensees, in each case, in connection with the Exploitation of Licensed Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates).

“**Proposing Party**” has the meaning set forth in Section 2.2(a) (New Applications).

“**Publication**” has the meaning set forth in Section 11.4 (Technical Publication).

“**Regulatory Approval**” means, with respect to a particular country or other jurisdiction and product, marketing authorization granted by the applicable Regulatory Authority in such country to Commercialize such product, including, where applicable, (a) pricing or reimbursement approval in such country or other jurisdiction, and (b) pre-

and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto).

“**Regulatory Approval Application**” means a New Drug Application filed with the FDA as described in 21 C.F.R. § 314 or any equivalent or corresponding application for Regulatory Approval (including for any applicable pricing and reimbursement approval) in any country or regulatory jurisdiction other than the U.S.

“**Regulatory Authority**” means, with respect to a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approvals of pharmaceutical products in such country or jurisdiction.

“**Regulatory Materials**” means Regulatory Approval Applications, investigational new drug applications, clinical trial applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to Exploit a Licensed Product in a particular country or jurisdiction.

“**Royalty Bearing Product**” means, on a Licensed Product-by-Licensed Product basis, with respect to a Licensed Product and each country in the Territory, any Licensed Product that is Covered by a Valid Claim included in any OPKO Patent Right at the time any share issuance or payment is owed pursuant to Sections 7.1, 7.3, 7.4(a) or 7.4(b) or at any time prior to or at the time of the First Commercial Sale with respect to payments owed pursuant to Section 7.5.

“**Royalty Payments**” has the meaning set forth in Section 7.5(a) (Royalty Rates).

“**Royalty Rate**” has the meaning set forth in Section 7.5(a) (Royalty Rates).

“**Royalty Report**” has the meaning set forth in Section 7.5(b) (Royalty Reports and Payments).

“**Royalty Term**” means, with respect to each country in the Territory, the period commencing on the First Commercial Sale of a Royalty Bearing Product in such country, and ending upon the latest to occur of: (a) the expiration, invalidation, or abandonment date of the last Patent Right included in the OPKO Patent Rights Covering such Royalty Bearing Product in such country; or (b) 10 years from First Commercial Sale of such Royalty Bearing Product in such country.

“**Sales Milestone Event**” has the meaning set forth in Section 7.4(b) (Sales Milestone Payments).

“**Sales Milestone Payment**” has the meaning set forth in Section 7.4(b) (Sales Milestone Payments).

[***]

“**Sublicensee**” means any Third Party to whom CAMP4 grants a sublicense of the rights granted to it under Section 2.1(b) (Sublicense Rights). Distributors, wholesalers, retailers, or other Third Party contractors engaged by or on behalf of CAMP4 to perform its obligations or exercise its rights under this Agreement on a fee-for-service basis, in each case, will not be considered Sublicensees.

“**Subscription Agreement**” has the meaning set forth in Section 7.2 (Equity Consideration).

“**Term**” has the meaning set forth in Section 12.1 (Term).

“**Terminated Product**” has the meaning set forth in Section 12.3(c) (Process for Termination).

“**Terminated Region**” has the meaning set forth in Section 12.3(c) (Process for Termination).

“**Territory**” means all countries worldwide.

“**Third Party**” means any individual, corporation, partnership, limited liability company, trust, unincorporated association, Governmental Authority, or other entity or body other than OPKO or CAMP4 or an Affiliate of either of them.

“**Third Party Claim**” has the meaning set forth in Section 8.6 (Third Party Claim).

“**Trademark**” means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo, business symbol or domain names, whether or not registered.

“**U.S.**” means the United States of America, including all possessions and territories thereof.

“**Valid Claim**” means a claim of (a) any issued and unexpired patent whose validity, enforceability, or patentability has not been affected by any of the following: (i) lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability; or (b) a pending patent application that is filed and prosecuted in good faith and no more than [***] years have elapsed from its earliest priority date.

ARTICLE 2 LICENSES

2.1 Licenses.

(a) OPKO License Grants to CAMP4

(i) OPKO, on behalf of itself and its Affiliates, hereby grants to CAMP4 and its Affiliates an exclusive (even as to OPKO), royalty-bearing, worldwide, license, with the right to grant and authorize sublicenses through multiple tiers in accordance with Section 2.1(b) (Sublicense Rights), under the OPKO Technology to Exploit the Licensed Compounds and Licensed Products in the Exclusive Field in the Territory. OPKO shall take any necessary action to cause its Affiliates to grant the license described in this Section 2.1(a) (OPKO License Grants to CAMP4).

(ii) OPKO, on behalf of itself and its Affiliates, hereby grants to CAMP4 and its Affiliates a non-exclusive, royalty-bearing, worldwide, license, with the right to grant and authorize sublicenses through multiple tiers in accordance with Section 2.1(b) (Sublicense Rights), under the OPKO Technology to Exploit the Licensed Compounds and Licensed Products in the Non-Exclusive Field in the Territory. OPKO shall take any necessary action to cause its Affiliates to grant the license described in this Section 2.1(a) (OPKO License Grants to CAMP4).

(b) Sublicense Rights. CAMP4 may grant sublicenses of the rights granted to it under Section 2.1(a) (OPKO License Grant to CAMP4) through multiple tiers to any Third Party. Each such sublicense will be consistent with the terms of this Agreement and will require such Sublicensee to comply with all applicable

terms of this Agreement. To the extent possible, CAMP4 shall notify OPKO as soon as practicable about any such sublicense and identify the terms thereof.

(c) [***].

2.2 New Applications.

(a) If after the [***] anniversary of the Effective Date, a Third Party (“**Proposing Party**”) notifies OPKO that it desires to obtain a license under the OPKO Technology with respect to [***] for exploitation in a particular indication in one or more countries in the Territory, but for which indication [***] are not, at such time, under Development by CAMP4 (each, a “**New Application**”), then OPKO may give written notice to CAMP4 of the Proposing Party’s proposal and shall include in such notification the identity of the Proposing Party and a description of the proposed New Application, including the indication and country(ies) proposed by the Proposing Party.

(b) CAMP4 shall have [***] days from receipt of the notice from OPKO regarding the New Application to give OPKO written notice stating whether CAMP4 elects to [***].

(c) If CAMP4 elects to [***] pursuant to clause (b), CAMP4 shall provide to OPKO [***]. [***] thereafter, CAMP4 will [***] of this Agreement.

(d) If CAMP4 elects to [***], either upon initial notification from OPKO or in connection with the [***], OPKO may [***]. If the Proposing Party requests a [***], then CAMP4 shall have [***] with such Proposing Party or any other Third Party.

(e) If CAMP4 [***] then [***]. If OPKO determines that the [***], then OPKO shall have [***], and provided further that [***].

2.3 Non-Compete. Notwithstanding anything to the contrary in this Agreement, including [***], during the Term, [***], and will [***], directly or indirectly, [***] (or [***] to do any of the foregoing) (collectively, [***]). If OPKO or any of its Affiliates undergoes a Change of Control with a Third Party, then OPKO will not be in breach of this Section 2.3, and such Third Party may, after such Change of Control, continue to conduct then ongoing [***], or commence the conduct of, the [***] with respect to Competitive Products that would otherwise constitute a breach of this Section 2.3 as long as: (A) no OPKO Technology or Confidential Information of CAMP4 is used by or on behalf of OPKO or its Affiliates in connection with any subsequent development, manufacture or commercialization of such Competitive Products, and (B) OPKO and its Affiliates institute commercially reasonable technical and administrative safeguards to ensure the requirements set forth in the foregoing clause (A) are met, including by creating “firewalls” between the personnel working on such Competitive Products and the personnel working or having worked on the Licensed Compounds and Licensed Products or having access to data from activities performed under this Agreement or Confidential Information of OPKO.

ARTICLE 3 LICENSED PRODUCT DEVELOPMENT

3.1 Overview. CAMP4 will, at [***], lead and have sole control over and decision-making authority for all Development activities for the Licensed Products in the Field in the Territory.

3.2 Development Diligence and Responsibilities. CAMP4 will, either directly or by or with an Affiliate or a Sublicensee, use Commercially Reasonable Efforts to Develop a Licensed Product in the Field in the Territory.

3.3 Technology Exchange and Use. After the Effective Date, pursuant to the technology transfer plan attached hereto as Schedule 3.3 (Technology Transfer Plan), OPKO will (or will cause its applicable Affiliate or, if applicable, Third Parties to), at [***], disclose and make available to CAMP4 or its designee, in whatever form CAMP4 may reasonably request, all OPKO Know-How, and any other Know-How Covered by any OPKO Patent Right, including all OPKO Know-How required to Manufacture the Licensed Compounds and Licensed Products, and any inventory of Licensed Compounds existing as of the Effective Date. Thereafter, OPKO will, at [***], disclose and make available to CAMP4 or its designee, in whatever form CAMP4 may reasonably request, any additional OPKO Know-How or other Know-How Covered by any OPKO Patent Right that arises during the Term. In addition, and without prejudice to the generality of [***] obligations of [***] under Section 4.1 (Overview) or the foregoing transfer obligations of OPKO, if CAMP4 reasonably requests that OPKO's representatives visit CAMP4's facilities for the purposes of (a) transferring to CAMP4 or its designee, the OPKO Know-How, or other Know-How, (b) CAMP4 or its designee acquiring expertise on the practical application of the OPKO Know-How or such Know-How, or (c) otherwise assisting CAMP4 or its designee with issues arising during Exploitation of the Licensed Compounds or Licensed Products or the use of the OPKO Know-How or such Know-How, then in each case ((a) – (c)), OPKO will send appropriate representatives to CAMP4's facilities, *and* [***] associated with such visit.

3.4 Development Reports. [***], CAMP4 will provide OPKO with a written report that sets forth a summary and timeline for all ongoing and planned Development activities for the Licensed Products for the next [***] period, and a high level summary of any material clinical results obtained by CAMP4 during the preceding [***] period. Such reports will be Confidential Know-How of CAMP4 and subject to the terms of ARTICLE 11 (Confidentiality).

ARTICLE 4 MANUFACTURING AND SUPPLY

4.1 Manufacturing. Commencing on the Effective Date, CAMP4 will have the exclusive right to Manufacture and supply Licensed Compounds and Licensed Products itself or through one or more Affiliates or Third Parties selected by CAMP4 in its sole discretion.

ARTICLE 5 REGULATORY MATTERS

5.1 Regulatory Responsibilities. Commencing on the Effective Date, CAMP4 will be the sponsor of, lead, and have sole control over and decision-making authority for, at [***], preparing, filing, obtaining, and maintaining Regulatory Approvals for the Licensed Compounds and Licensed Products in the Territory and conducting all associated regulatory activities and communications for the Licensed Compounds and Licensed Products in the Field in the Territory. Ownership of all right in and to all Regulatory Approvals directed to any Licensed Compound or Licensed Product in each country of the Territory will be held in the name of CAMP4 or its Affiliate, designee, or Sublicensee.

5.2 Cooperation. Upon CAMP4's reasonable request, OPKO will provide CAMP4 with reasonable assistance and cooperation to enable CAMP4 to obtain Regulatory Approval for a Dravet Product in the Territory. Without limiting the foregoing, as requested by CAMP4, at CAMP4's expense, OPKO will provide [***] to CAMP4 in preparing regulatory filings for a Dravet Product in the Territory and make information Controlled by OPKO or its Affiliates available to CAMP4 to the extent necessary or useful in connection with such regulatory filings. Upon CAMP4's reasonable request and at [***], OPKO will support the Development of a Dravet Product in the Territory by providing Regulatory Authorities with access to, and the right to audit, any data or other Know-How and associated documents that are in OPKO's Control and are relied on by CAMP4 in its regulatory filings for a Dravet Product.

5.3 Notification of Threatened Action. OPKO will immediately notify CAMP4 of any information it receives regarding any threatened or pending action, inspection or communication by or from any Regulatory Authority that may affect or otherwise relate to the Development, Commercialization, or Regulatory Approval of a Licensed Compound or Licensed Product in the Territory.

ARTICLE 6 COMMERCIALIZATION

6.1 Commercialization Diligence. Following receipt of Regulatory Approval of a Licensed Product in a country in the Territory, CAMP4 will, either directly or by or with an Affiliate or a Sublicensee, use [***] to Commercialize such Licensed Product in the Field in such country.

6.2 Responsibility for Commercialization in the Territory. CAMP4 will [***] and [***] and [***] for, at [***], Commercialization of the Licensed Products in the Field in the Territory.

6.3 Commercialization Updates. CAMP4 will provide OPKO with an annual report summarizing its Commercialization activities for the Licensed Products in the Field in the Territory. Such reports will be Confidential Know-How of CAMP4 and subject to the terms of ARTICLE 11 (Confidentiality).

ARTICLE 7 COMPENSATION

7.1 Upfront Consideration. Within 10 days of the Effective Date, CAMP4 will pay OPKO a one-time up-front fee of \$1,500,000.

7.2 Equity Consideration. Within 10 days of the Effective Date, CAMP4 will issue to OPKO 3,373,008 shares (the "Initial Shares") of CAMP4's Series A Prime Preferred Stock pursuant to, and in accordance with the terms and conditions of, a Subscription Agreement in substantially the form attached hereto as Schedule 7.2

(Subscription Agreement) (the “Subscription Agreement”). Additional shares of CAMP4’s preferred stock will be issued in the following amounts (“Contingent Shares”) within [***] days of the following (each a “Contingent Milestone Event”) events: (i) following the [***] that is a [***], 5,782,299 shares (which number of shares shall be appropriately adjusted in the event of any stock dividend, stock split, recapitalization, consolidation or combination) of CAMP4’s Series A Prime Preferred Stock (or such number of shares of any class or series of capital stock of CAMP4 into which such Series A Prime Preferred Stock has been converted or exchanged prior to the occurrence of the Contingent Milestone Event at the exchange ratio at which such Series A Prime Preferred Stock has been so converted or exchanged), or (ii) following [***] that is a [***], 1,082,248 shares (which number of shares shall be appropriately adjusted in the event of any stock dividend, stock split, recapitalization, consolidation or combination) of CAMP4’s Series A Prime Preferred Stock (or such number of shares of any class or series of capital stock of CAMP4 into which such Series A Prime Preferred Stock has been converted or exchanged prior to the occurrence of the Contingent Milestone Event at the exchange ratio at which such Series A Prime Preferred Stock has been so converted or exchanged). Contingent Shares, if any, will be issued pursuant to a subscription agreement in substantially the form as the Subscription Agreement or such other customary documentation requested by the CAMP4. If CAMP4 has undergone a Change of Control prior to the time that CAMP4 has become obligated to issue the Contingent Shares, then OPKO will be entitled to receive the consideration that it would have received in such Change of Control transaction if it had held the Contingent Shares immediately prior to such Change of Control. If the first Contingent Milestone Event is [***], then the amount of Contingent Shares to be issued upon [***] shall be [***] issued in the [***]. Notwithstanding the foregoing, if the [***], no [***] for any Other Product.

7.3 Annual License Fee. Solely in the event that no IND-enabling study has been initiated with respect to any Non-Dravet Product prior to the [***] anniversary of the Effective Date [***] a fee of [***] within [***] days of such date and within [***] days of [***] anniversary of the Effective Date until any such study is initiated; provided that, [***] may elect not to pay such [***] fee [***], either when initially owed or at any such [***] anniversary, and upon written notice of such election to OPKO, then all licenses and other rights granted to CAMP4 pursuant to Section 2.1(a) (OPKO License Grant to CAMP4) with respect to Non-Dravet Products will terminate.

7.4 Milestone Payments.

(a) Development Milestone Payments. CAMP4 will pay to OPKO the following one-time Development milestone payments in accordance with the procedure set forth in Section 7.4(c) (Notice; Payment) after the first achievement by or on behalf of CAMP4 or its Affiliates of the milestone events as set forth in Table 7.4(a) below (each, a “**Development Milestone Event**”). Each milestone payment set forth in Table (a) (each, a “**Development Milestone Payment**”) is payable once for Dravet Products (*i.e.*, the first time the milestone event is achieved for a Royalty Bearing Product that is a Dravet Product) and once for each Other Product (*i.e.*, the first time the milestone event is achieved for each Royalty Bearing Product that is an Other Product). The maximum Development Milestone Payments payable under this Section (a) (Development Milestone Payments) is \$3,500,000 for Dravet Products that are Royalty Bearing Products, and \$4,000,000 for each Other Product that is a Royalty Bearing Product.

Table 7.4(a) – Development Milestones		
<i>Development Milestone Event</i>	<i>Development Milestone Payments for Dravet Products that are Royalty Bearing Products</i>	<i>Development Milestone Payments for each Other Product that is a Royalty Bearing Product</i>
(i) [***]	[***]	[***]
(ii) [***]	[***]	[***]

(b) Sales Milestone Payments. CAMP4 will pay to OPKO the following one-time, sales milestone payments in accordance with the procedure set forth in Section 7.4(c) (Notice; Payment) after the end of the first Calendar Year in which the sales milestone events set forth in Table 7.4(b) below are achieved (each, a “**Sales Milestone Event**”). Each sales milestone payment set forth in Table (b) (each, a “**Sales Milestone Payment**”) is payable once for Dravet Products (i.e., the first time the milestone event is achieved for the Royalty Bearing Products that are Dravet Products) and once for each Other Product (i.e., the first time the milestone event is achieved for each Royalty Bearing Product that is an Other Product). The maximum net sales milestone amount payable under this Section (b) (Sales Milestone Payments) is \$90,000,000 for Dravet Products that are Royalty Bearing Products, \$90,000,000 for each Other Product that is a Royalty Bearing Product.

Table 7.4(b) – Sales Milestones		
<i>Sales Milestone Event</i>	<i>Sales Milestone Payment for Dravet Products that are Royalty Bearing Products</i>	<i>Sales Milestone Payment for each Other Product that is a Royalty Bearing Product</i>
(i) Calendar Year Net Sales of Royalty Bearing Products in the Territory greater than [***]	[***]	[***]
(ii) Calendar Year Net Sales of Royalty Bearing Products in the Territory greater than [***]	[***]	[***]
(iii) Calendar Year Net Sales of Royalty Bearing Products in the Territory greater than [***]	[***]	[***]

(c) Notice; Payment. CAMP4 will provide OPKO with written notice upon the achievement of each milestone events set forth in this Section 7.4 (Milestone Payments), such written notice to be provided (a) with respect to any Development Milestone Event, within [***] days after such achievement and (b) with respect to any Sales Milestone Event, within [***] days of the end of the Calendar Year in which such milestone event is

first achieved. Following receipt of such written notice, OPKO will promptly invoice CAMP4 for the applicable milestone and CAMP4 will make the appropriate milestone payment within [***] days after receipt of such invoice.

7.5 Royalty Payments.

(a) Royalty Rates. On a Royalty Bearing Product-by-Royalty Bearing Product and country-by-country basis, during the Royalty Term for such Royalty Bearing Product in such country, CAMP4 will pay to OPKO [***] of all Royalty Bearing Products (the “**Royalty Rate**”, and such payments, the “**Royalty Payments**”), subject to adjustment as set forth in Section 7.6 (Royalty Payment Adjustments).

(b) Royalty Reports and Payments. Within [***] days following the end of each Calendar Quarter, commencing upon the first Calendar Quarter in which the First Commercial Sale of Royalty Bearing Product is made anywhere by CAMP4 or its Affiliate or Sublicensee in the Territory, CAMP4 will provide OPKO with a report of the Net Sales of each Royalty Bearing Product in each country or other jurisdiction in the Territory during the applicable Calendar Quarter and a calculation of the amount of the Royalty Payment due on such Net Sales for such Calendar Quarter (the “**Royalty Report**”). [***], CAMP4 will pay in Dollars the Royalty Payment due to OPKO under Section 7.5 (Royalty Payments) with respect to Net Sales by CAMP4, its Affiliates and Sublicensees for such Calendar Quarter.

7.6 Royalty Payment Adjustments.

(a) [*] for Lack of Valid Claims.** Notwithstanding Section 7.5 (Royalty Payments), on a Royalty Bearing Product-by-Royalty Bearing Product and country-by-country basis, if, during the Royalty Term for a Royalty Bearing Product in a country in the Territory, such Royalty Bearing Product sold in such country is not Covered by a Valid Claim included in the OPKO Patent Rights in such country, then the Royalty Payments payable to OPKO for such Royalty Bearing Product in such country during such Royalty Term will be [***] of the amount otherwise payable under Section 7.5 (Royalty Payments).

(b) [*] for Third Party Enabling Technology.**

(i) In the event that CAMP4 makes any payment to any Third Party in consideration for a grant of rights (whether by acquisition or license) under any Patent Rights or Know-How that is necessary or reasonably useful in order to Exploit any Royalty Bearing Product in the Territory, then CAMP4 may [***] of such payment(s) from the [***] otherwise payable under this ARTICLE 7 (Compensation). Notwithstanding the foregoing, in the event that CAMP4 becomes a direct licensee of the intellectual property rights licensed to OPKO under the [***], then CAMP4 shall be entitled to [***] under any such direct license [***] under this ARTICLE 7 (Compensation) after all other permitted [***] have been applied to such payments under this Agreement, and the limitation on [***] described in Section 7.6(d) [***] shall not apply to any [***] pursuant to this sentence.

(ii) All financial and other obligations, including royalties, due from OPKO to any Third Parties pursuant to any agreement to which OPKO is a party as of the Effective Date for or in respect of the OPKO Technology, the Licensed Compounds, or Licensed Product(s) (including [***]) will be the [***].

(c) [*] for Generic Entry.** If, on a Royalty Bearing Product-by-Royalty Bearing Product and country-by-country basis, a Generic Product with respect to a Royalty Bearing Product is sold in a country, then the Royalty Payments payable to OPKO for such Royalty Bearing Product in such country will be [***] of the amount [***] under Section 7.5 (Royalty Payments).

(d) [***]. Notwithstanding any provision to the contrary herein, under no circumstances will the combined effect of all [***] under Sections 7.6(a) ([***] for Lack of Valid Claims), 7.6(b) ([***] for Third Party Enabling Technology), and 7.6(c) ([***] for Generic Entry) on a country-by-country and Royalty Bearing Product-by-Royalty Bearing Product basis, [***] the effective Royalty Payments [***] under this Agreement for any Calendar Year below [***] of the Royalty Payments that would otherwise be payable pursuant to Section 7.5 (Royalty Payments) for such Royalty Bearing Product in such country; *provided* that CAMP4 may [***] permitted in accordance with this Section 7.6 (Royalty Payment Adjustments), and may [***] Royalty Payments [***] in any subsequent Calendar Quarter until the amount of [***].

7.7 Upfront Payment Share. CAMP4 will pay to OPKO the applicable percentage set forth in Table 7.7 below of any upfront payments received by CAMP4 or its Affiliates in consideration for (a) the grant by CAMP4 or its Affiliate of a sublicense under CAMP4’s rights in the OPKO Technology solely with respect to one or more Non-Dravet Products, or (b) the assignment of CAMP4’s rights and obligations solely with respect to Non-Dravet Products under this Agreement in accordance with Section 14.5 (Assignment), where such sublicense or assignment is executed prior to the [***], and excluding any portion of such upfront payment that is expressly designated (including in a corresponding budget) in the applicable sublicense or assignment as an [***] of Development activities [***] for Licensed Products.

Table 7.7 – Upfront Payment Share	
<i>Investment Status</i>	<i>Upfront Payment Percentage</i>
If, at the time the applicable sublicense or assignment is executed, CAMP4 and its Affiliates have invested [***] in the Non-Dravet Products that are subject to such sublicense or assignment	[***]%
If, at the time the applicable sublicense or assignment is executed, CAMP4 and its Affiliates have invested [***] in the Non-Dravet Products that are subject to such sublicense or assignment	[***]%

7.8 Foreign Exchange. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party will convert any amount expressed in a foreign currency into Dollar equivalents using its or its Affiliate’s or Sublicensee’s standard conversion methodology consistent with GAAP.

7.9 Payment Method; Late Payments. CAMP4 will make all payments due hereunder in Dollars to OPKO by check or wire transfer of immediately available funds into an account designated by OPKO. Any late payment by CAMP4 will bear interest, to the extent permitted by applicable Law, at an [***] or the highest rate permitted by applicable Law (whichever is lower), computed from the date such payment was due until the date CAMP4 makes the payment.

7.10 Records. CAMP4 will keep (and will ensure that its Affiliates and, with respect to CAMP4, Sublicensees keep) such records as are required to determine, in accordance with GAAP, and this Agreement, the sums or credits due under this Agreement, including Net Sales. CAMP4 will retain all such books, records and accounts until three years after the end of the period to which such books, records, and accounts pertain.

7.11 Audits . OPKO may have a nationally recognized, independent certified public accountant, acceptable to CAMP4, access and examine during normal business hours, and upon at least 30 days’ prior written notice, only those records of CAMP4 (and its Affiliates, as applicable) retained pursuant to Section 7.10 (Records) as may be reasonably necessary to determine, with respect to any Calendar Year ending not more than three years before OPKO’s request, the correctness or completeness of any report or payment made under this Agreement. Prior to commencing its work pursuant to this Agreement, any such independent certified public accountant conducting an

audit will enter into an appropriate and reasonable confidentiality agreement with CAMP4 pursuant to this Section 7.11 (Audits). The foregoing right of review may be exercised only once in any one-year period and only once with respect to each such periodic report and payment. Such accountant will disclose only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information will be shared and such results will be subject to ARTICLE 11 (Confidentiality). If the audit report concludes that additional amounts were owed by CAMP4, then CAMP4 will pay the additional amounts within [***] days after the date on which such audit report is delivered to both Parties, [***] or the highest rate permitted by applicable law, computed from the date the underpayment was made until the date of payment to OPKO of the underpayment. If the audit report concludes that excess payments were made by CAMP4, then CAMP4 may withhold such amounts from any payment that is owed by CAMP4 to OPKO under this Agreement. [***] will [***] of the performance of any such audit, unless such audit discloses [***] of the amount due, in which case [***] will [***] of such audit. The results of such audit will be [***].

7.12 Taxes.

(a) Taxes on Income. Each Party will pay all taxes imposed on its share of income arising directly or indirectly from the efforts of, or the receipt of any payment by, such Party under this Agreement.

(b) Tax Withholding. If any taxes are required to be withheld by CAMP4 with respect to an amount payable to OPKO pursuant to this Agreement, then CAMP4 will: (i) withhold such taxes from the payment made to OPKO; (ii) timely remit the withheld taxes to the proper taxing authority; (iii) send evidence of the payment to OPKO; (iv) send the applicable tax withholding certificates to OPKO; and (v) reasonably assist OPKO in its efforts to obtain a refund of, or credit for, such tax payment in accordance with Section 7.12(c) (Tax Cooperation). Any amount actually withheld and remitted by CAMP4 to a taxing authority pursuant to this Section 7.12(b) (Tax Withholding) will be treated for all purposes of this Agreement as paid to OPKO. No amount will be withheld, or a reduced amount will be withheld, as applicable, if, in accordance with Section 7.12(c) (Tax Cooperation), OPKO furnishes CAMP4 with the necessary tax forms and other documents prescribed by applicable Law a reasonable time prior to the date the applicable payment is due and such forms or document identify that the relevant payment is exempt from tax or subject to a reduced tax rate (as applicable). In the event that a Governmental Authority retroactively determines that a payment made by CAMP4 to OPKO pursuant to this Agreement should have been subject to withholding or similar (or to additional withholding or similar) taxes, and CAMP4 remits such withholding or similar taxes to such Governmental Authority, including any interest and penalties that may be imposed thereon (together with the tax paid, the “Amount”), then CAMP4 may invoice OPKO for the Amount (which will be payable by OPKO no later than 60 days after its receipt of such invoice), *provided* that CAMP4 has provided documentation to OPKO evidencing the requirement for payment and payment by CAMP4. If OPKO fails to pay the Amount as provided in the foregoing, then CAMP4 may withhold the Amount from any of CAMP4’s future payment obligations under this Agreement or pursue reimbursement of the Amount by any other available remedy.

(c) Tax Cooperation. CAMP4 agrees to cooperate with OPKO and to use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of the upfront payment, Royalty Payments, milestone payments and other payments made by CAMP4 to OPKO under this Agreement. OPKO will provide CAMP4 with any tax forms that may be reasonably necessary in order for CAMP4 not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty a reasonable time prior to the date the applicable payment is due. CAMP4 will provide OPKO with reasonable assistance to enable the recovery, as permitted by Law, of withholding taxes, value added taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of OPKO.

7.13 No Joint Venture. For clarity, notwithstanding the Royalty Payments described in Section 7.5 (Royalty Payments), the Parties acknowledge that they are not sharing any losses arising from the Parties' performance of their respective obligations or exercise of their respective rights under this Agreement and nothing in this ARTICLE 7 (Compensation) will be interpreted or construed to create an association, joint venture or partnership between the Parties.

ARTICLE 8 INTELLECTUAL PROPERTY MATTERS

8.1 Ownership of Existing Know-How and Patent Rights. As between the Parties, all Know-How and Patent Rights Controlled by a Party prior to the Effective Date or conceived, discovered, developed, or otherwise made separate and apart from this Agreement, will be owned by the Party Controlling such Know-How and Patent Rights.

8.2 Ownership of Sole Inventions. [***] will own [***], whether or not [***] in the course of conducting its activities under this Agreement, together with all intellectual property rights therein.

8.3 Inventorship. Except as otherwise set forth in this Agreement, inventorship of patentable inventions conceived, discovered, developed, or otherwise made during the performance of activities pursuant to this Agreement will be determined in accordance with U.S. patent laws.

8.4 Prosecution of Patent Rights.

(a) CAMP4 Responsibility. Within [***] days following the Effective Date, as between the Parties, CAMP4 will assume responsibility for and control of the preparation, filing, prosecution, and maintenance of the OPKO Patent Rights in the Territory. As between the Parties, [***] in connection with the preparation, filing, prosecution, or maintenance of any OPKO Patent Rights.

(b) CAMP4 Abandonment. If CAMP4 decides to abandon any OPKO Patent Right in the Territory, then CAMP4 will provide OPKO with prompt written notice of such decision and OPKO may thereafter be responsible for the prosecution and maintenance of such OPKO Patent Rights at [***]. Such Abandoned or transferred patent will no longer be within the licensed OPKO Patent Rights.

(c) Cooperation. With respect to all OPKO Patent Rights, the Parties will work together to effectively transfer the patent docket prosecution and maintenance responsibilities within the OPKO Patent Rights to the Prosecuting Party and will solicit the other Party's comments prior to filing any OPKO Patent Rights in the Territory, including by providing the other Party copies of all patent filings and all material communications to and from the relevant patent authority sufficiently in advance of submitting such filings or responses so as to allow a reasonable opportunity for the other Party to review and comment thereon, and the prosecuting Party will consider the other Party's reasonable comments with respect thereto in good faith. Each Party will provide the other Party reasonable assistance and cooperation in the patent preparation, filing, prosecution and maintenance efforts provided in this Section 8.4 (Prosecution of Patent Rights), including executing any other required documents or instruments for such prosecution. [***] per Calendar Year or as [***], CAMP4 shall provide a report of the pending and issued patent docket along with a schedule of maintenance fee payments due and made during such Calendar Year for the OPKO Patents.

(d) Patent Right Term Extensions and Patent Right Listings. CAMP4 will be responsible for making decisions regarding patent term extensions, supplementary patent protection certificates, and any other extensions that are now or become available in the future, wherever applicable, for any and all OPKO Patent Rights

in the Territory. CAMP4 will have the sole right to make all filings with Regulatory Authorities in the Territory with respect to all OPKO Patent Rights, including as required or allowed (i) in the U.S., in the FDA's Orange Book, and (ii) outside the U.S., under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents.

8.5 Patent Right and Know-How Enforcement in the Territory

(a) Notification. If either Party becomes aware of any existing or threatened infringement of any of OPKO Patent Right in the Field in the Territory by a Third Party with respect to a Licensed Compound or Licensed Product (including any generic version thereof) or the Exploitation of any product that is competitive with a Licensed Product ("**Competitive Infringement**"), then such Party will promptly notify the other Party in writing to that effect. For the avoidance of doubt, the term "Competitive Infringement" includes any counterclaims alleging that an OPKO Patent Right is invalid or unenforceable or that a product or process does not infringe or misappropriate an OPKO Patent Right.

(b) Enforcement Rights. For any Competitive Infringement, OPKO will share with CAMP4 all information available to it regarding such actual or alleged infringement. As between the Parties, with respect to OPKO Patent Rights, CAMP4 will have the first right, but not obligation, to bring an appropriate suit or other action against any Person engaged in such Competitive Infringement, and OPKO will take appropriate actions to enable CAMP4 to commence such suit or take such actions. If CAMP4 fails to commence enforcement of the OPKO Patent Rights against a Competitive Infringement within a period of 90 days after a request from OPKO to do so, then OPKO may commence a suit or take action to enforce such OPKO Patent Rights against such Competitive Infringement; *provided* that, if CAMP4 notifies OPKO during such 90day period that it is electing in good faith not to institute any proceeding to enforce any OPKO Patent Rights against such Competitive Infringement for strategic reasons intended to maintain the commercial value of the relevant OPKO Patent Rights or any Licensed Compound or Licensed Product Covered thereby or relating thereto, then OPKO will not have the right to initiate and control any proceeding to enforce such OPKO Patent Rights against such Competitive Infringement. OPKO will not settle any claim, suit, or action that it brought under Section 8.5(b) (Enforcement Rights) with respect to OPKO Patent Rights in any manner that imposes any costs or liability on, or involves any admission by, CAMP4 or reduces the scope, validity or enforceability of any OPKO Patent Right.

(c) Collaboration. Each Party will provide to the enforcing Party reasonable assistance in such enforcement, at such [***], including joining such action as a party plaintiff if required by applicable Law to pursue such action in accordance with this Section 8.5 (Patent Right and Know-How Enforcement in the Territory). The enforcing Party will keep the other Party regularly informed of the status and progress of such enforcement efforts, will reasonably consider the other Party's comments on any such efforts. The non-enforcing Party may obtain separate representation in such matter by counsel of its own choice and at its own expense, but such Party will at all times cooperate fully with the enforcing Party.

(d) Expenses and Recoveries.

(i) The enforcing Party bringing a claim, suit, or action under Section 8.5(b) (Enforcement Rights) will [***] by such Party, or [***], as a result of such claim, suit, or action or as a result of any counterclaims relating to such claim, suit, or action.

(ii) If the enforcing Party [***] with respect to any [***] pursuant to Section 8.5(b) (Enforcement Rights) and [***] in such claim, suit, action, or counterclaim thereof, then such recovery will be allocated [***] incurred by the Parties [***], and any remaining amounts will be [***] in the following [***]:[***].

(iii) If the enforcing Party is [***] with respect to any OPKO Patent Rights pursuant to Section 8.5(b) (Enforcement Rights) and [***] in such claim, suit, action, or counterclaim thereof that are related to [***], such recovery will be allocated [***] by the Parties in such litigation, and any [***].

8.6 Third Party Claims. Subject to the indemnification rights or obligations of a Party under ARTICLE 10 (Indemnification), if a Licensed Product used or sold by CAMP4 or its Affiliates or Sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent Right (each such claim or assertion a "Third Party Claim") granted by a jurisdiction within the Territory, then CAMP4 will have the [***] such Third Party Claim at [***]. OPKO will, [***], reasonably assist CAMP4 in such defense, including assisting with document collection and production and cooperating with all discovery requests, and will at all times cooperate fully with CAMP4.

8.7 Trademarks. CAMP4 will have the [***] right to determine and own all Product Trademarks to be used with respect to the Exploitation of the Licensed Products in the Territory. CAMP4 will own all rights, title, and interests in and to all Product Trademarks in the Territory. OPKO will not, and will not permit its Affiliates to, (a) use in their respective businesses, any Trademark that is confusingly similar to, misleading, or deceptive with respect to or that dilutes any (or any part) of any Product Trademarks, and (b) do any act that endangers, destroys, or similarly affects, in any respect, the value of the goodwill pertaining to the Product Trademarks. OPKO will not, and will not permit its Affiliates to, attack, dispute, or contest the validity of or ownership of any Product Trademark anywhere in the Territory or any registrations issued or issuing with respect thereto.

ARTICLE 9 REPRESENTATIONS AND WARRANTIES; COVENANTS

9.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows, as of the Effective Date:

(a) Corporate Existence. It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it was incorporated or formed;

(b) Corporate Power, Authority, and Binding Agreement . It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder. It has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to enforcement of remedies under applicable bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies;

(c) No Conflict. The execution and delivery of this Agreement, the performance of such Party's obligations hereunder and the rights, licenses, and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of Law; (ii) do not and will not conflict with or violate the certificate of incorporation, by-laws or other organizational documents of such Party; (iii) do not and will not conflict with, violate, breach, or constitute a material default under any contractual obligations of such Party or any of its Affiliates; and (iv) neither Party is under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder;

(d) No Consents. No authorization, consent, or approval of a Third Party, nor any license, permit, exemption, of or filing or registration with or notification to any court or Governmental Authority is or will be necessary for the (i) valid execution, delivery or performance of this Agreement by either Party; or (ii) the consummation by each Party of the transactions contemplated hereby;

(e) Other Rights. Neither Party nor any of their respective Affiliates is a party to or otherwise bound by any oral or written contract or agreement that will result in any other person obtaining any interest in, or that would give to any other person any right to assert any claim in or with respect to, any of such Party's rights under this Agreement; and

(f) No Debarment. None of such Party's employees, consultants or contractors:

(i) is debarred under Section 306(a) or 306(b) of the FD&C Act or by the analogous Laws of any Regulatory Authority;

(ii) has, to such Party's knowledge, been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U.S.C. §§1320a-7(a), 1320a-7(b)(1)-(3), or pursuant to the analogous Laws of any Regulatory Authority, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or has been convicted of a criminal offense that falls within the scope of 42 U.S.C. §1320a-7 but not yet excluded, debarred, suspended or otherwise declared ineligible), or excluded, suspended or debarred by a Regulatory Authority from participation, or otherwise ineligible to participate, in any procurement or non-procurement programs.

9.2 Additional Representations and Warranties of CAMP4 CAMP4 represents and warrants to OPKO as follows, as of the Effective Date:

(a) Capitalization; Valid Issuance. CAMP4 has an authorized capitalization as set forth in the capitalization table shared with OPKO on the day hereof, and all the outstanding shares of capital stock of CAMP4 have been duly authorized and validly issued and are fully paid and non-assessable. None of the outstanding shares of capital stock of CAMP4 were issued in violation of the preemptive or other similar rights of any security holder of CAMP4. The Initial Shares and Contingent Shares have been duly authorized and, when issued and delivered in accordance with this Agreement for the consideration expressed herein will be validly issued, fully paid and nonassessable and will be free and clear of all liens, charges and encumbrances of any nature whatsoever except for restrictions on transfer under this Agreement and under applicable Federal and state securities laws.

9.3 Additional Representations and Warranties of OPKO. OPKO represents and warrants to CAMP4 as follows, as of the Effective Date:

(a) OPKO Patent Rights Title; Encumbrances (i) It is the sole and exclusive owner of, and Controls, the entire right, title and interest in the Patent Rights listed on Schedule 1.66 (OPKO Patent Rights), Part I (the "**Owned Patent Rights**") and has no rights or interest in any Patent Rights that would be included in the OPKO Patent Rights but for OPKO not Controlling such Patent Rights; (ii) it is the sole and exclusive licensee of, and Controls, the Patent Rights listed on Schedule 1.66 (OPKO Patent Rights), Part II (the "**In-Licensed Patent Rights**"), in each case ((i) and (ii)), free and clear from any mortgages, pledges, liens, security interests, options, conditional and installment sale agreements, encumbrances, charges, or claims of any kind; (iii) the Owned Patent

Rights and In-Licensed Patent Rights constitute all Patent Rights owned, Controlled, or held for use by OPKO or its Affiliates that are necessary or reasonably useful to Exploit the Licensed Compounds or any Licensed Product in the Territory; (iv) no Third Party has taken any action before any patent or trademark office (or similar Governmental Authority) alleging that any of the OPKO Technology is invalid or unenforceable or that, if successful, would render any of the OPKO Technology invalid or unenforceable; and (v) OPKO is entitled to grant the licenses specified herein.

(b) OPKO Know-How. It owns or Controls the OPKO Know-How and has the right to grant the licenses under the OPKO Know-How to CAMP4 on and the terms set forth in this Agreement and has no rights or interest in any Know-How that would be included in the OPKO Know-How but for OPKO not Controlling such Know-How. OPKO has the right to use and disclose (in each case, under appropriate circumstances of confidentiality) the OPKO Know-How free and clear of any mortgages, pledges, liens, security interests, options, conditional and installment sale agreements, encumbrances, charges, or claims of any kind.

(c) Notice of Infringement or Misappropriation. OPKO has not received written notice and is not aware of any claim or threatened claim nor, to OPKO's knowledge, is there any basis for any non-asserted claim or threatened claim, that (i) any Exploitation of Licensed Product by OPKO before the Effective Date infringed or misappropriated the intellectual property rights of a Third Party in the Territory or (ii) the practice of the OPKO Technology licensed to CAMP4 under this Agreement infringes or misappropriates, would infringe or misappropriate, or would otherwise conflict or interfere with, any intellectual property rights of any Third Party;

(d) Prosecution and Maintenance of OPKO Patent Rights. The OPKO Patent Rights are being diligently prosecuted in the respective patent offices in the Territory in accordance with applicable Law, and the OPKO Patent Rights have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment;

(e) Pending Patent Right Applications. In respect of the pending patent applications included in the OPKO Patent Rights, OPKO and its Affiliates have submitted all relevant references, documents, and information of which it and the inventors are aware to the relevant patent examiner at the relevant patent office;

(f) Inventors. Each of the Patent Rights listed on Schedule 1.66 (OPKO Patent Rights) properly identifies each and every inventor of the claims thereof as determined in accordance with the Laws of the jurisdiction in which such Patent Right is issued or such application is pending;

(g) Infringement by Third Parties. No claim is pending, and OPKO and any of its Affiliates and, to OPKO's knowledge, any Third Party collaborator, has not received from a Third Party notice of a claim or threatened claim to the effect that any granted Patent Rights within the OPKO Technology licensed to CAMP4 under this Agreement is invalid or unenforceable;

(h) Compliance with Laws. OPKO has complied in all respects with all Laws in connection with the prosecution of the OPKO Patent Rights, including the duty of candor owed to any patent office pursuant to such Laws;

(i) No Grant of Rights. Except pursuant to the License Agreement dated February 21, 2018 by and between Roche Innovation Center Copenhagen A/S and OPKO, neither OPKO nor any of its Affiliates has granted any rights with respect to the OPKO Technology or any Licensed Compound or Licensed Product in the Exclusive Field in the Territory (including by granting any covenant not to sue with respect thereto) to any Person other than the rights granted to CAMP4 pursuant to this Agreement;

(j) No Unauthorized Use. Neither OPKO nor any of its Affiliates has received any written notice of any unauthorized use, infringement, or misappropriation by any Person, including any current or former employee or consultant of OPKO or any of its Affiliates, of the OPKO Technology or any Licensed Compound or Licensed Product;

(k) Assignment. Each Person who has or has had any rights in or to any Owned Patent Rights or any OPKO Know-How has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Owned Patent Rights and OPKO Know-How to OPKO;

(l) [***]. The [***] represents all written agreements [***].

(m) Third Party Confidentiality. To OPKO's knowledge, no Third Party has any OPKO Know-How in its possession or Control that is not subject to continuing obligations of confidentiality owed to OPKO or any of its Affiliates, and to OPKO's knowledge, no breach of such confidentiality has been committed by any Third Party;

(n) Good Practices. The Development and Manufacture of Licensed Product has been carried out in accordance with all applicable Laws in all material respects, including GLP, GCP and GMP, as applicable;

(o) Regulatory Matters. Except as disclosed on Schedule 9.3 (OPKO Disclosures), OPKO has not filed any Regulatory Materials with any Regulatory Authority with respect to the Licensed Products. OPKO also has not had any formal communications with Regulatory Authorities in any country in the Territory about the potential approval path for the Licensed Products and has not received any formal guidance or correspondence related thereto;

(p) Third Party Payments. Other than pursuant to the [***], there are [***] that will be required to be [***] as a result of the Exploitation of the Licensed Compounds or Licensed Products that arise out of any agreement to which OPKO or any of its Affiliates is a party or, to OPKO's knowledge, at all;

(q) Material Facts. OPKO has furnished or made available to CAMP4 or its agents or representatives all (i) information requested by CAMP4, (ii) material reports, applications, statements, documents, registrations, filings, notifications, amendments, supplements and submissions required to be filed under applicable Laws, and (iii) notices of adverse findings, notices of inspectional observations, audit reports, establishment inspection reports, statements of deficiency, or warning or untitled letters issued to OPKO, each as received from any Governmental Authority, and any other documents received from any Governmental Authority that state, describe, or allege a lack of compliance with any applicable Laws or other regulatory requirements, in each case ((i) through (iii)), concerning the Licensed Compounds, the Licensed Products, and the OPKO Technology.

9.4 Covenants.

(a) No Violation. Neither OPKO nor any of its Affiliates will enter into any obligation to any Person, contractual or otherwise, that, by its terms, directly conflicts with or is inconsistent with in any material respect of the terms of this Agreement or would materially impede the fulfillment of OPKO's obligations hereunder.

(b) OPKO Technology. OPKO and its Affiliates will (i) maintain (A) exclusive ownership and Control of all OPKO Technology owned by OPKO or its Affiliates at any time during the Term and (B) Control of all OPKO Technology in-licensed by OPKO or its Affiliates at any time during the Term, and (ii) not assign,

transfer, encumber, or otherwise grant any Third Party any rights with respect thereto that would conflict with, limit the scope of, or adversely affect the rights granted to CAMP4 under this Agreement.

(c) [***].

9.5 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, AND OTHER THAN IN CIRCUMSTANCES CONSTITUTING FRAUD, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL SUCH ADDITIONAL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

ARTICLE 10 INDEMNIFICATION

10.1 Indemnification by OPKO. OPKO will, at its sole expense, defend, indemnify, and hold CAMP4, and its Affiliates and their respective officers, directors, employees, consultants, and agents (the “**CAMP4 Indemnitees**”) harmless from and against any and all damages, losses, liabilities, taxes, costs, expenses (including court costs and reasonable attorneys’ fees and expenses), and recoveries (collectively, “**Losses**”) arising from claims, suits, and proceedings brought by Third Parties (collectively, “**Claims**”) arising from or relating to (a) the breach of any of OPKO’s obligations under this Agreement, including OPKO’s representations and warranties, covenants, or agreements, (b) the Development, Commercialization, Manufacture, or other Exploitation of the Licensed Compounds or Licensed Products in the Territory by or on behalf of OPKO or any OPKO Indemnitee prior to, during, or after the Term, or (c) the willful misconduct or grossly negligent acts of OPKO or any OPKO Indemnitee. The foregoing indemnity obligation will not apply (i) to the extent that such Claims or Losses arise out of or result from the fraud, gross negligence or willful misconduct of CAMP4 or its Affiliates, or any related breach by CAMP4 of its representations, warranties, or covenants hereunder; or (ii) to Claims or Losses for which CAMP4 has an obligation to indemnify OPKO pursuant to Section 10.1 (Indemnification by OPKO).

10.2 Indemnification by CAMP4. CAMP4 will, at its sole expense, defend, indemnify and hold OPKO and its Affiliates and their respective officers, directors, employees, consultants, and agents (the “**OPKO Indemnitees**”) harmless from and against any and all Losses arising from Claims arising from or relating to (a) the breach of any of CAMP4’s obligations under this Agreement, including CAMP4’s representations and warranties, covenants, or agreements, (b) the Development, Commercialization, Manufacture, or other Exploitation of the Licensed Products by or on behalf of CAMP4 or its Affiliates or its or their respective Sublicensees, or (c) the willful misconduct or grossly negligent acts of CAMP4 or any CAMP4 Indemnitee. The foregoing indemnity obligation will not apply (i) to the extent that such Claims or Losses arise out of or result from the fraud, gross negligence or willful misconduct of OPKO or its Affiliates, or any related breach by OPKO of its representations, warranties, or covenants hereunder; or (ii) to Claims or Losses for which OPKO has an obligation to indemnify CAMP4 pursuant to Section 10.1 (Indemnification by OPKO).

10.3 Indemnification Procedures. The Party claiming indemnity under this ARTICLE 10 (Indemnification) (the “**Indemnified Party**”) will give written notice to the Party from whom indemnity is being sought (the “**Indemnifying Party**”) [***] after learning of such Claim or Loss; *provided, however*, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby. The Indemnified Party will provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party’s

expense, in connection with the defense of a Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided, however*, except as otherwise set forth in Section 8.6 (Third Party Claim) with respect to infringement Claims, the Indemnifying Party may control and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money and includes a complete release of claims for the Indemnified Party. The Indemnified Party will not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim within [***] days after receipt of written notice thereof from the Indemnified Party, then (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, but will obtain any consent (not to be unreasonably withheld) from, the Indemnifying Party in connection therewith) and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this ARTICLE 10 (Indemnification).

10.4 Limitation of Liability. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOST PROFITS, LOST REVENUES, OR LOST BUSINESS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES OR WHETHER SUCH PARTY SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.4 (LIMITATION OF LIABILITY) IS INTENDED TO LIMIT OR RESTRICT (A) THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 10.1 (INDEMNIFICATION BY OPKO) OR 10.2 (INDEMNIFICATION BY CAMP4), (B) DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS IN ARTICLE 11 (CONFIDENTIALITY), (C) DAMAGES AVAILABLE FOR OPKO'S BREACH OF SECTION 2.3, (D) DAMAGES AVAILABLE FOR OPKO'S BREACH OF ANY REPRESENTATIONS OR WARRANTIES CONTAINED IN SECTION 9.3(a) (OPKO PATENT RIGHTS TITLE; ENCUMBRANCES) OR 9.3(f) (INVENTORS) OR (E) DAMAGES ARISING FROM A PARTY'S FRAUD, GROSS NEGLIGENCE, WILLFUL MISCONDUCT, OR OMISSION.

10.5 Insurance. Within [***] days after the Effective Date, each Party will procure, and will maintain during the Term and for a period of at least two years after the last commercial sale of any Licensed Product for which it is responsible hereunder, and at its cost, reasonable insurance with a reputable solvent insurer against liability and other risks associated with its activities contemplated by this Agreement in an amount appropriate for its business and products of the type that are the subject of this Agreement, and for its obligations under this Agreement. Notwithstanding the foregoing, such obligation may be satisfied by a program of self-insurance.

ARTICLE 11 CONFIDENTIALITY

11.1 Confidentiality. Each Party agrees that, during the Term and for a period of [***] years thereafter, it and its Affiliates will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than to exercise its rights or perform its obligations under this Agreement any Confidential Information furnished to it or its Affiliate by the other Party or its Affiliate pursuant to this Agreement, except to the extent expressly authorized by this Agreement or as otherwise agreed to in writing by the Parties. Each Party will further require its Affiliates, and its and their respective directors, officers, employees, agents, consultants, sublicensees, contractors, partners, acquirors, assignees, and distributors who receive the other Party's Confidential

Information to agree, in writing, to be bound by duties and obligations of confidentiality and non-use no less stringent than those contained in this Section 11.1 (Confidentiality).

Notwithstanding the obligations set forth in Section 11.1 (Confidentiality), a Party or its Affiliate may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing, prosecuting, enforcing, or defending Patent Right rights as contemplated by this Agreement; (ii) to comply with the requirements of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of a Licensed Product or submission of information to tax or other Governmental Authorities; (iii) for prosecuting or defending litigation as contemplated by this Agreement; or (iv) complying with applicable Law;

(b) such disclosure is reasonably necessary to its officers, directors, employees, agents, consultants, contractors, licensees, sublicensees, attorneys, accountants, sources of debt or equity financing, insurers, or licensors who need to know such information in order for such Party to perform its obligations or exercise its rights under this Agreement; provided that, in each case, the disclosees are bound by written obligations of confidentiality and non-use no less stringent than those of this Agreement with a reasonable duration based on customary terms;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner or such Third Parties' advisors or representatives for the sole purpose of evaluating an actual or potential investment, acquisition, or other business relationship; provided that, in each case, the disclosees are bound by written obligations of confidentiality and non-use no less stringent than to those of this Agreement with a reasonable duration based on customary terms, and provided, further, that in the case of any such disclosure of Confidential Information to any actual or potential competitor of either Party, all competitively sensitive information (including, for the avoidance of doubt, all financial information) herein will be redacted until, subject to applicable Laws, the execution of a definitive agreement with such actual or potential competitor to implement a transaction with the receiving Party is imminent; or

(d) such disclosure is reasonably necessary to comply with applicable Laws, including regulations promulgated by applicable security exchanges, court order, administrative subpoena, or other order.

Notwithstanding the foregoing, if a Party or its Affiliate is required to make a disclosure of the other Party's Confidential Information pursuant to Section 11.1(a) or 11.1(d) (Authorized Disclosures), then such Party will (i) promptly notify the other Party of such required disclosure, (ii) give the other Party an opportunity to seek confidential treatment and, upon the other Party's request, such Party and its Affiliates will use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure, and (iii) if the other Party is unsuccessful in its efforts pursuant to subsection (ii), disclose only that portion of the Confidential Information that such Party is legally required to disclose.

11.2 Secrecy of OPKO Know-How. Without limiting the generality of Section 11.1 (Confidentiality) and notwithstanding any provision to the contrary set forth in this Agreement, during the Term, OPKO will protect, and will cause, to the extent applicable, its Affiliates, and its and their respective officers, directors, employees, and agents to protect, the secrecy and confidentiality of the OPKO Know-How and unpublished Patent Rights using at least the same degree of care as it uses to prevent the disclosure of its own other confidential information of like importance and in any event a reasonable duty of care.

11.3 Residual Knowledge. Notwithstanding any provision to the contrary set forth in this Agreement, Confidential Information will not include any knowledge, technique, experience, or Know-How that is retained in

the unaided memory of any authorized representative of the receiving Party after having access to such Confidential Information.

11.4 Technical Publication. Neither OPKO nor any of its Affiliates will submit for publication, publish or present an abstract or presentation (each of the foregoing, a “**Publication**”) relating to any Licensed Compound or Licensed Product without prior review and written approval by CAMP4.

11.5 Publicity; Terms of Agreement.

(a) Terms of Agreement. The Parties agree that the existence and terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 11.5 (Publicity; Terms of Agreement).

(b) Required Disclosures. The Parties acknowledge that either or both Parties may be obligated to file under Laws a copy of this Agreement with the U.S. Securities or other Governmental Authorities. Each Party may make such a required filing and will use reasonable efforts to request confidential treatment of the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party under applicable Law. In the event of any such filing, each Party will provide the other Party with a copy of this Agreement marked to show provisions for which such Party intends to seek confidential treatment and will reasonably consider and incorporate the other Party’s comments thereon to the extent consistent with the legal requirements and provided within five Business Days after provision of such copy (or such shorter period of time as may be required to comply with applicable Law), with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

11.6 Prior Confidentiality Agreements. CAMP4 and OPKO are each parties to that certain Mutual Confidentiality Agreement by and among the Parties dated February 24, 2021 (the “**Prior CDA**”). This Agreement, including this ARTICLE 11, will supersede the Prior CDA and all Confidential Information disclosed pursuant to the Prior CDA will be considered Confidential Information under this Agreement and subject to the obligations set forth in this ARTICLE 11.

11.7 Unauthorized Use. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party’s Confidential Information, then it will promptly notify the other Party of such unauthorized use or disclosure.

ARTICLE 12
TERM AND TERMINATION

12.1 Term. This Agreement becomes effective on the Effective Date, and, unless sooner terminated as specifically provided in this Agreement, continues in effect on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of the Royalty Term for a Licensed Product in a country and expires in its entirety upon the expiration of the Royalty Term for the last Licensed Product in the last country in the Territory (the “**Term**”).

12.2 Termination for Convenience by CAMP4. CAMP4 may terminate this Agreement in its entirety or on a Licensed Product-by-Licensed Product or country-by-country basis upon [***] days’ prior written notice to OPKO.

12.3 Termination for Breach.

(a) Notice. If a Party materially breaches this Agreement with respect to a Licensed Product or country in the Territory (other than any obligations to make any payments due under this Agreement) (the “**Breaching Party**”), then the other Party (the “**Non-Breaching Party**”) may give written notice to the Breaching Party identifying such material breach in reasonable detail (a “**Default Notice**”) and the Breaching Party will cure such material breach within [***] days after delivery of the Default Notice, *provided* that if such material breach is not reasonably capable of cure within such [***]-day period and if the Breaching Party continues to use reasonable efforts to cure such material breach, then the [***] day cure period will be automatically extended for an additional [***] days, or such [***].

(b) Process for Disputes. If a Non-Breaching Party provides a Default Notice to the Breaching Party pursuant to Section 12.3(a) (Notice) as a result of a material breach (or alleged material breach) then, on or before the end of the cure period therefor, either Party will have the right to refer the matter to the designated executive officer of OPKO and the designated executive officer of CAMP4 (or their respective designees) (the “**Executive Officers**”) pursuant to Section 13.1 (Referral of Disputes to Parties Executive Officers) before terminating this Agreement in accordance with the process set forth in Section 12.3(c) (Process for Termination). The cure period set forth in Section 12.3(a) (Notice) will be tolled during the pendency of such dispute, and all of the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

(c) Process for Termination. If the material breach is so cured within the remainder of the cure period, whether without or after the procedure set forth in Section 12.3(b) (Process for Disputes), then this Agreement will remain in full force and effect. If (i) the material breach is not cured within the remainder of the cure period or settled pursuant to Section 12.3(b) (Process for Disputes) and (ii) OPKO is the Non-Breaching Party, then, within [***] days after the end of such cure period, the Non-Breaching Party will send written notice to the Breaching Party advising of the termination of this Agreement with respect to all or a portion of the Territory, as the case may be, in accordance with this Section 12.3(c) (Process for Termination), or if CAMP4 is the Non-Breaching Party, advising OPKO of its election provided in this Section 12.3(c) (Process for Termination), and such termination (or such other election, if applicable) will be effective upon the Breaching Party’s receipt of such written notice. Notwithstanding any provision to the contrary set forth in this Agreement, if an uncured material breach by CAMP4 relates to one or more countries (but not all countries) and one or more Licensed Products (but not all Licensed Products), then except as provided in the subsequent provisos of this Section 12.3(c) (Process for Termination), OPKO will not have the right to terminate this Agreement in its entirety, but will only have the right to terminate this Agreement with respect to the countries to which such material breach relates. Any region or country (as applicable) with respect to which this Agreement is terminated will be referred to herein as a “**Terminated Region**” (and if this Agreement is terminated in its entirety, then all countries will be Terminated Regions) and any Licensed Product with respect to which this Agreement is terminated will be referred to herein as a “**Terminated Product**” (and if this Agreement is terminated in its entirety, then all Licensed Products will be Terminated Products).

(d) Alternative Remedies to Termination. If OPKO fails to cure its material breach of this Agreement within the applicable time period set forth in Section 12.3(a) and such breach is not settled pursuant to Section 12.3(b) (Process for Disputes), CAMP4 may elect, in lieu of terminating this Agreement as a result of such material breach, the alternative remedy provisions of this Section 12.3(d) (Alternative Remedies to Termination) by providing written notice of such election to OPKO, in which case, this Agreement will continue in full force and effect and (i) the milestone payments under Section 7.4 (Milestone Payments) will be [***] and royalty payments under Section 7.5 (Royalty Payments) will be [***] (after giving effect to all other applicable [***] under Section 7.6 (Royalty Payment Adjustments)), and (ii) CAMP4’s reporting obligations under Section 3.4 (Development Reports) and 6.3 (Commercialization Updates) will terminate. [***].

12.4 Effect of Expiration or Termination.

(a) **Expiration.** Upon expiry of the Term on a country-by-country and Licensed Product-by-Licensed Product basis, all rights and licenses granted by OPKO under this Agreement with respect to such Licensed Product or country will remain in effect in accordance with their terms and will become irrevocable, unrestricted, perpetual, and fully paid up.

(b) **Effects of Termination.** Upon the termination of this Agreement in its entirety, on a country-by-country basis or on a Licensed Product-by-Licensed Product basis, then each of the following will apply with respect to such applicable Terminated Region or Terminated Product:

(i) **Termination of CAMP4's Licenses.** As of the effective date of termination of this Agreement with respect to a Licensed Product, all licenses and all other rights granted by OPKO to CAMP4 under Section 2.1(a) (OPKO License Grant to CAMP4) with respect to the Terminated Products will terminate, and CAMP4 shall have no further rights under the OPKO Patent Rights or OPKO Know How to develop, manufacture or market the Terminated Products or any product containing the Terminated Products.

(ii) **Reversion Rights.** At OPKO's written request, CAMP4 [***] under which CAMP4 will:

(A) transfer to OPKO or OPKO's designee, [***]: (1) possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including all Regulatory Approvals and pricing and reimbursement approvals) in CAMP4's control and relating solely to the development, manufacture or commercialization of the Terminated Product and all product trademarks then being used in connection with Terminated Product, other than CAMP4's corporate trademarks; and (2) all safety data and other adverse event data in CAMP4's Control and relating solely to the Terminated Product. In addition, OPKO shall have the right to purchase all raw materials and ingredients and Terminated Product in CAMP4'S possession or control at the applicable cost of goods of such raw materials, ingredients or Terminated Product. Notwithstanding the foregoing, CAMP4 shall be entitled to sell any completed inventory of Terminated Product which remain on hand as of the date of the termination, and to sell new inventory to the extent necessary to satisfy its contractual and legal obligations, so long as CAMP4 pays to OPKO the royalties applicable to said subsequent sales in accordance with the terms and conditions as set forth in this Agreement; provided that no sales shall be permitted after the expiration of [***] months after the date of termination. CAMP4 will execute all documents and take all such further actions, as may be reasonably requested by OPKO in order to give effect to the preceding sentences as soon as practicable.

(B) in the event of termination of this Agreement by OPKO [***], CAMP4 will grant to OPKO a royalty-bearing, worldwide, non-exclusive, sublicensable, license under any Know-How conceived, discovered, developed, or otherwise made solely or jointly by or on behalf of by CAMP4 or its Affiliates in the performance of activities under this Agreement to the extent constituting an improvement of the OPKO Know-How, and any Patent Rights Controlled by CAMP4 that Cover such improvement Know-How, solely to the extent necessary or reasonably useful to manufacture, market, sell or use such Terminated Product as it existed as of the effective date of termination, bearing royalties on the worldwide Net Sales of such Terminated Product (including Net Sales by OPKO's Affiliates and licensees) as set forth below in Table 12.4(b)(ii)(B) and subject to Section 7.9 (Payment Method; Late Payments), 7.10 (Records), 7.11 (Audits) and 7.12 (Taxes), applied *mutatis mutandis* (replacing references to CAMP4 with OPKO and *vice versa*):

TABLE 12.4(b)(ii)(B)		
Stage of Applicable Terminated Product at Time of Termination	Royalty Rate as a Percentage (%) of Net Sales [***]	Royalty Rate as a Percentage (%) of Net Sales [***]
Prior to the [***]with respect to such Terminated Product	[***]	[***]
Following the [***] with respect to such Terminated Product	[***]	[***]

(iii) Return of Confidential Information. Each Party will promptly return to the other Party (or as directed by such other Party destroy and certify to such other Party in writing as to such destruction) all of such other Party’s Confidential Information provided by or on behalf of such other Party hereunder that is in the possession or control of such Party (or any of its Affiliates, or Sublicensees), except that such Party will have the right to retain copies of intangible Confidential Information of such other Party for legal purposes. Notwithstanding any provision to the contrary set forth in this Agreement, the receiving Party of any Confidential Information will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

(iv) Other Remedies. Termination or expiration of this Agreement for any reason will not release either Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason will not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

12.5 Rights in Bankruptcy.

(a) All rights and licenses now or hereafter granted by OPKO to CAMP4 under or pursuant to this Agreement, including the licenses granted to CAMP4 pursuant to Section 2.1 (Licenses), are, for all purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to “intellectual property” as defined in the Bankruptcy Code. Upon the occurrence of any insolvency event with respect to OPKO, OPKO agrees that CAMP4, as CAMP4 of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code. Without limiting the generality of the foregoing, OPKO and CAMP4 intend and agree that any sale of OPKO’s assets under Section 363 of the Bankruptcy Code will be subject to CAMP4’s rights under Section 365(n), that CAMP4 cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser “free and clear” of CAMP4’s rights under this Agreement and Section 365(n) without the express, contemporaneous consent of CAMP4. Further, each Party agrees and acknowledges that all payments by CAMP4 to OPKO hereunder, other than the Royalty Payments pursuant to Section 7.5 (Royalty Payments), do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. OPKO will, during the term of this Agreement, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property. OPKO and CAMP4 acknowledge and agree that “embodiments” of intellectual property within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples and inventory, research studies, and data, regulatory approvals. If (i) a case under the Bankruptcy Code is commenced by or against OPKO, (ii) this Agreement is rejected as provided in the Bankruptcy Code, and (iii) CAMP4 elects to retain its rights hereunder as provided in

Section 365(n) of the Bankruptcy Code, then OPKO (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

() provide to CAMP4 all such intellectual property (including all embodiments thereof) held by OPKO and such successors and assigns, or otherwise available to them, immediately upon CAMP4's written request. Whenever OPKO or any of its successors or assigns provides to CAMP4 any of the intellectual property licensed hereunder (or any embodiment thereof) pursuant to this Section 12.5(a) (Rights in Bankruptcy), CAMP4 will have the right to perform OPKO's obligations hereunder with respect to such intellectual property, but neither such provision nor such performance by CAMP4 will release OPKO from liability resulting from rejection of the license or the failure to perform such obligations; and

(i) not interfere with CAMP4's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property (including such embodiments), including any right to obtain such intellectual property (or such embodiments) from another entity, to the extent provided in Section 365(n) of the Bankruptcy Code.

(b) All rights, powers, and remedies of CAMP4 provided herein are in addition to and not in substitution for any and all other rights, powers, and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code with respect to OPKO. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under Bankruptcy Code Section 365(n):

(i) the right of access to any intellectual property (including all embodiments thereof) of OPKO, or any Third Party with whom OPKO contracts to perform an obligation of OPKO under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import, or export of Licensed Products; and

(ii) the right to contract directly with any Third Party to complete the contracted work.

12.6 Survival. Termination or expiration of this Agreement (either in its entirety or with respect to one (1) or more countries) for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to such termination or expiration. For clarity, termination for breach by either Party under Section 12.3 (Termination for Breach), will not preclude the terminating Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. Notwithstanding anything to the contrary, the following provisions will survive any expiration or termination of this Agreement: ARTICLE 1 (Definitions), ARTICLE 10 (Indemnification), ARTICLE 11 (Confidentiality), ARTICLE 13 (Dispute Resolution), ARTICLE 14 (Miscellaneous), and Sections 7.8 (Foreign Exchange), 7.9 (Payment Method; Late Payments), 7.10 (Records), 7.11 (Audits), 7.12 (Taxes), 8.1 (Ownership of Existing Know-How and Patent Rights), 8.2 (Ownership of Sole Inventions), 8.4(c) (Cooperation), 8.6 (Third Party Claim) (but with respect to 8.4(c) (Cooperation) and 8.6 (Third Party Claim), solely with respect to actions that are ongoing at the time of such termination), 12.4 (Effect of Expiration or Termination) and 12.6 (Survival). Except as expressly set forth herein, all rights and obligations of the Parties hereunder will terminate on the expiration or termination of this Agreement.

ARTICLE 13 DISPUTE RESOLUTION

13.1 Referral of Disputes to Parties Executive Officers. In the event of any disputes, controversies or differences between the Parties, arising out of, in relation to, or in connection with this Agreement, including any alleged failure to perform, or breach, of this Agreement, or any issue relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement a (“**Dispute**”), then, upon the written request of either Party, the Dispute will be first submitted to the Executive Officers of each Party for attempted resolution by good faith negotiations within [***] days. If the Dispute is not resolved within [***] days following the written request for amicable resolution, then (a) if the Dispute is an intellectual property Dispute relating to the validity, enforceability or inventorship of any Patent Right or Trademark rights covering the Manufacture, use, importation, offer for sale, sale or other Exploitation of Licensed Product, then such Dispute will be resolved pursuant to Section 13.6 (Patent Right and Trademark Disputes), and (b) any other Dispute will be resolved pursuant to Section 13.2 (Litigation).

13.2 Litigation. Any unresolved Dispute that was subject to Section 13.1 (Referral of Disputes to Parties Executive Officers) will be brought exclusively in a court of competent jurisdiction, federal or state, located in Delaware and in no other jurisdiction. Each Party hereby irrevocably consents to personal jurisdiction and venue in, and irrevocably agrees to service of process issued or authorized by any such court in any such action or proceeding. The Parties hereby irrevocably waive any objection which they may now have or hereafter have to the laying of venue in the federal or state courts of Delaware in any such action or proceeding, and hereby irrevocably waive and agree not to plead or claim in any such court that any such action or proceeding brought in any such court has been brought in an inconvenient forum. The Parties hereby agree that any final judgment rendered by any such federal or state court of Delaware in any action or proceeding involving any Dispute, from which no appeal can be or is taken, may be enforced by the prevailing Party in any court of competent jurisdiction.

13.3 Equitable Relief. Notwithstanding any provision to the contrary set forth in this Agreement, in the event of an actual or threatened breach of a Party’s obligations under this Agreement, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis.

13.4 Governing Law. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof are governed by and construed under the Laws of the State of Delaware, without giving effect to any choice of law principles that would require the application of the Laws of a different state. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

13.5 Waiver of Jury Trial. Each Party hereby waives to the fullest extent permitted by applicable Law, any right it may have to a trial by jury in respect to any litigation directly or indirectly arising out of, under or in connection with this Agreement. Each Party (a) certifies that no representative, agent or attorney of any other Party has represented, expressly or otherwise, that such other Party would not, in the event of litigation, seek to enforce that foregoing waiver, and (b) acknowledges that it and the other Parties have been induced to enter into this Agreement, as applicable, by, among other things, the mutual waivers and certifications in this Section 13.5 (Waiver of Jury Trial).

13.6 Patent Right and Trademark Disputes. Notwithstanding Section 13.1 (Referral of Disputes to Parties Executive Officers), any Dispute relating to the validity or enforceability of any Patent Right or Trademark rights covering the Manufacture, use, importation, offer for sale, sale or other Exploitation of any Licensed Product will be submitted to a court of competent jurisdiction in the country in which such Patent Right or Trademark rights were granted or arose, and any Dispute relating to inventorship will be resolved based on an independent inventorship analysis under the United States patent law by a patent attorney jointly selected by the Parties, and the Parties hereby agree to be bound by such independent inventorship analysis and will share equally the expenses of such patent attorney.

Ropes & Gray LLP
800 Boylston Street, Prudential Tower
Boston, MA 02199
Attention: Marc Rubenstein

14.4 No Strict Construction; Interpretation; Headings. The language in this Agreement is to be construed in all cases according to its fair meaning. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation,” (c) the word “will” will be construed to have the same meaning and effect as the word “shall,” (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person’s or entity’s successors and assigns, (f) the words “herein,” “hereof,” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word “notice” means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent,” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or,” and (l) references to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered “Section 2.2” would be part of “Section 2”, and references to “Section 2.2” would also refer to material contained in the subsection described as “Section 2.2(a)”).

14.5 Assignment. This Agreement and the rights and obligations of each Party under this Agreement will not be assignable, delegable, transferable, pledged, or otherwise disposed of by either Party without the prior written consent of the other Party; *provided, however*, that either Party may assign or transfer this Agreement in whole or in part together with all of its rights and obligations hereunder, without such consent, to (a) an Affiliate or (b) a successor in interest in connection with a Change of Control; provided, that CAMP4 will have the right to terminate its reporting obligations under Section 3.4 (Development Reports) and 6.3 (Commercialization Updates) in the event that OPKO assigns or transfers this Agreement in whole or in part in connection with a Change of Control of OPKO. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.5 (Assignment) is null, void, and of no legal effect.

14.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party’s obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party’s Affiliate of any of such Party’s obligations under this Agreement is a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party’s Affiliate.

14.7 Further Assurances and Actions. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably

necessary to consummate or implement expeditiously the express purposes and intent contemplated by this Agreement.

14.8 No Third Party Beneficiaries. Except for the rights to indemnification provided for under ARTICLE 10 (Indemnification) above, all rights, benefits and remedies under this Agreement are solely intended for the benefit of OPKO and CAMP4, and except for such rights to indemnification expressly provided pursuant to ARTICLE 10 (Indemnification), no Third Party will have any rights whatsoever to: (a) enforce any obligation contained in this Agreement; (b) seek a benefit or remedy for any breach of this Agreement; or (c) take any other action relating to this Agreement under any legal theory, including actions in contract, tort (including negligence, gross negligence and strict liability), or as a defense, setoff or counterclaim to any action or claim brought or made by the Parties.

14.9 Severability. Each of the provisions contained in this Agreement will be severable, and the unenforceability of one will not affect the enforceability of any others or of the remainder of this Agreement. If any one or more of the provisions of this Agreement, or the application thereof in any circumstances, is held to be invalid, illegal, or unenforceable in any respect for any reason, the Parties will negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; *provided, however*, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions of this Agreement will not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto will be enforceable to the fullest extent permitted by Law. The Parties agree that if a court finds that the scope of any one or more of the provisions contained in this Agreement will, for any reason, be invalid, illegal, excessively broad, unreasonable or unenforceable in any respect, then the court may modify such provision and render it reasonable.

14.10 No Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver, delay or the failure of any Party to enforce or exercise any term, condition or part of this Agreement at any time or in any one or more instances will not be deemed to be or construed as a waiver of the same or any other term, condition or part, nor will it forfeit any rights, power or privilege to future enforcement thereof. No single or partial exercise of any right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. To the maximum extent permitted by Law, (a) no claim or right arising out of this Agreement or any of the documents referred to in this Agreement can be discharged by one Party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other Party; (b) no waiver that may be given by a Party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one Party will be deemed to be a waiver of any obligation of that Party or of the right of the Party giving such notice or demand to take further action without notice or demand as provided in this Agreement or the documents referred to in this Agreement. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

14.11 Relationship of the Parties. Neither Party will have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party will have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, OPKO and CAMP4 will be independent contractors and the legal relationship between the Parties will not constitute a partnership, joint venture, or agency, including for all tax purposes. This Agreement is not a partnership or deemed partnership or an Association of Person ("AOP") agreement. Nothing in this Agreement will be construed to establish a relationship of partners, AOPs or joint venturers between the Parties. Neither CAMP4 nor OPKO will

make any statements, representations, or commitments of any kind, or to take any action that is binding on the other, in each case, without the prior consent of the other Party to do so.

14.12 English Language. This Agreement was prepared and executed in the English language, which language governs the interpretation of, and any dispute regarding, the terms of this Agreement.

14.13 Expenses. Each of the Parties will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.

14.14 Acknowledgments and Representations. Each of the Parties acknowledges and represents that it has been represented by legal counsel regarding its rights and obligations under this Agreement, has participated in the drafting hereof and fully understands the terms and conditions contained herein.

14.15 Counterparts **14.16** . This Agreement may be executed in one or more counterparts, each of which is an original, but all of which together constitute one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format (“PDF”) sent by electronic mail. In addition, PDF signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding, and delivery of a PDF signature by any Party will constitute due execution and delivery of this Agreement.

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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: July 29, 2021

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.

Chief Executive Officer

CERTIFICATIONS

I, Adam Logal, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of OPKO Health, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 29, 2021

/s/ Adam Logal

Adam Logal

Senior Vice President and Chief Financial Officer

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

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

The Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 (the “Form 10-Q”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 29, 2021

/s/ Phillip Frost, M.D.

Phillip Frost, M.D.
Chief Executive Officer

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

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

The Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 (the “Form 10-Q”) of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 29, 2021

/s/ Adam Logal

Adam Logal

Senior Vice President and Chief Financial Officer