

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended July 31, 2019

Commission file number 0-11254

**ANIXA BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

11-2622630

(I.R.S. Employer  
Identification No.)

3150 Almaden Expressway, Suite 250  
San Jose, CA

(Address of principal executive offices)

95118

(Zip Code)

(408) 708-9808

(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 exchange on which registered
Common Stock, par value \$.01 per share	ANIX	NASDAQ Capital Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

On September 5, 2019 the registrant had outstanding 20,207,261 shares of Common Stock, par value \$.01 per share, which is the registrant's only class of common stock.

## **TABLE OF CONTENTS**

### **PART I. FINANCIAL INFORMATION**

<b><u>Item 1.</u></b>	<b><u>Financial Statements.</u></b>	
	<u>Condensed Consolidated Balance Sheets as of July 31, 2019 (Unaudited) and October 31, 2018</u>	1
	<u>Condensed Consolidated Statements of Operations (Unaudited) for the nine months ended July 31, 2019 and 2018</u>	2
	<u>Condensed Consolidated Statements of Operations (Unaudited) for the three months ended July 31, 2019 and 2018</u>	3
	<u>Condensed Consolidated Statement of Shareholders' Equity (Unaudited) for the nine months ended July 31, 2019</u>	4
	<u>Condensed Consolidated Statement of Shareholders' Equity (Unaudited) for the three months ended July 31, 2019</u>	5
	<u>Condensed Consolidated Statement of Shareholders' Equity (Unaudited) for the nine months ended July 31, 2018</u>	6
	<u>Condensed Consolidated Statement of Shareholders' Equity (Unaudited) for the three months ended July 31, 2018</u>	7
	<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the nine months ended July 31, 2019 and 2018</u>	8
	<u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u>	9
<b><u>Item 2.</u></b>	<b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations.</u></b>	25
<b><u>Item 3.</u></b>	<b><u>Quantitative and Qualitative Disclosures About Market Risk.</u></b>	32
<b><u>Item 4.</u></b>	<b><u>Controls and Procedures.</u></b>	32
<b><u>PART II. OTHER INFORMATION</u></b>		
<b><u>Item 1.</u></b>	<b><u>Legal Proceedings.</u></b>	33
<b><u>Item 1A.</u></b>	<b><u>Risk Factors.</u></b>	33
<b><u>Item 2.</u></b>	<b><u>Unregistered Sales of Equity Securities and Use of Proceeds.</u></b>	33
<b><u>Item 3.</u></b>	<b><u>Defaults Upon Senior Securities.</u></b>	33
<b><u>Item 4.</u></b>	<b><u>Mine Safety Disclosures.</u></b>	33
<b><u>Item 5.</u></b>	<b><u>Other Information.</u></b>	33
<b><u>Item 6.</u></b>	<b><u>Exhibits.</u></b>	34
	<b><u>SIGNATURES</u></b>	35

---

**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements.****ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	(Unaudited)	
	July 31, 2019	October 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,396,853	\$ 3,055,890
Short-term investments in certificates of deposit	2,100,000	2,000,000
Receivables	1,072	306,991
Prepaid expenses and other current assets	129,644	175,491
Total current assets	<u>6,627,569</u>	<u>5,538,372</u>
Patents, net of impairment of \$1,001,729 and \$582,979, respectively, and accumulated amortization of \$2,034,382 and \$1,615,632, respectively	-	837,500
Property and equipment, net of accumulated depreciation of \$86,789 and \$53,799, respectively	215,137	72,670
Total assets	<u>\$ 6,842,706</u>	<u>\$ 6,448,542</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 567,778	\$ 582,012
Accrued expenses	875,771	683,099
Total current liabilities	<u>1,443,549</u>	<u>1,265,111</u>
Commitments and contingencies (Note 9)		
Equity:		
Shareholders' equity:		
Preferred stock, par value \$100 per share; 19,860 shares authorized; no shares issued or outstanding	-	-
Series A convertible preferred stock, par value \$100 per share; 140 shares authorized; no shares issued or outstanding	-	-
Common stock, par value \$.01 per share; 48,000,000 shares authorized; 20,162,851 and 18,908,632 shares issued and outstanding, respectively	201,628	189,086
Additional paid-in capital	185,326,706	175,415,931
Accumulated deficit	(179,729,770)	(170,170,209)
Total shareholders' equity	<u>5,798,564</u>	<u>5,434,808</u>
Noncontrolling interest (Note 1)	(399,407)	(251,377)
Total equity	<u>5,399,157</u>	<u>5,183,431</u>
Total liabilities and equity	<u>\$ 6,842,706</u>	<u>\$ 6,448,542</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	For the Nine Months Ended	
	July 31,	
	2019	2018
Revenue	\$ 250,000	\$ 1,112,500
Operating costs and expenses:		
Inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion	166,250	767,180
Amortization of patents	418,750	243,972
Research and development expenses (including non-cash share-based compensation expenses of \$2,567,294 and \$2,668,315, respectively)	4,602,239	4,380,137
General and administrative expenses (including non-cash share-based compensation expenses of \$2,335,218 and \$2,558,701, respectively)	4,405,385	4,602,555
Impairment in carrying amount of patent asset (Note 1)	418,750	-
Total operating costs and expenses	<u>10,011,374</u>	<u>9,993,844</u>
Loss from operations	(9,761,374)	(8,881,344)
Interest income	53,783	29,780
Loss before income taxes	(9,707,591)	(8,851,564)
Provision for income taxes	-	-
Net loss	(9,707,591)	(8,851,564)
Less: Net loss attributable to noncontrolling interest	(148,030)	(158,032)
Net loss attributable to common shareholders	<u>\$ (9,559,561)</u>	<u>\$ (8,693,532)</u>
Net loss per common share attributable to common shareholders:		
Basic and diluted	\$ (0.49)	\$ (0.50)
Weighted average common shares outstanding:		
Basic and diluted	19,638,833	17,257,546

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	For the Three Months Ended	
	July 31,	
	2019	2018
Revenue	\$ -	\$ 362,500
Operating costs and expenses:		
Inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion	-	241,157
Amortization of patents	41,875	81,324
Research and development expenses (including non-cash share-based compensation expenses of \$338,449 and \$2,472,489, respectively)	1,085,574	2,942,071
General and administrative expenses (including non-cash share-based compensation expenses of \$492,449 and \$2,155,844 respectively)	1,056,963	2,703,752
Total operating costs and expenses	2,184,412	5,968,304
Loss from operations	(2,184,412)	(5,605,804)
Interest income	18,364	12,228
Loss before income taxes	(2,166,048)	(5,593,576)
Provision for income taxes	-	-
Net loss	(2,166,048)	(5,593,576)
Less: Net loss attributable to noncontrolling interest	(26,020)	(116,650)
Net loss attributable to common shareholders	\$ (2,140,028)	\$ (5,476,926)
Net loss per common share attributable to common shareholders:		
Basic and diluted	\$ (0.11)	\$ (0.30)
Weighted average common shares outstanding:		
Basic and diluted	20,100,915	18,431,025

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY  
FOR THE NINE MONTHS ENDED JULY 31, 2019 (UNAUDITED)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity	Non- controlling Interest	Total Equity
	Shares	Par Value					
Balance, October 31, 2018	18,908,632	\$ 189,086	\$ 175,415,931	\$(170,170,209)	\$ 5,434,808	\$ (251,377)	\$ 5,183,431
Stock option compensation to employees and directors	-	-	2,808,910	-	2,808,910	-	2,808,910
Stock options and warrants issued to consultants	-	-	139,161	-	139,161	-	139,161
Common stock issued upon exercise of stock options	40,000	400	102,100	-	102,500	-	102,500
Restricted stock award compensation to employee pursuant to stock incentive plan	-	-	1,954,441	-	1,954,441	-	1,954,441
Common stock issued pursuant to employee stock purchase plan	5,411	54	18,506	-	18,560	-	18,560
Common stock issued in at-the-market offering, net of offering expenses of \$264,186	1,208,808	12,088	4,887,657	-	4,899,745	-	4,899,745
Net loss	-	-	-	(9,559,561)	(9,559,561)	(148,030)	(9,707,591)
Balance, July 31, 2019	<u>20,162,851</u>	<u>\$ 201,628</u>	<u>\$ 185,326,706</u>	<u>\$(179,729,770)</u>	<u>\$ 5,798,564</u>	<u>\$ (399,407)</u>	<u>\$ 5,399,157</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY  
FOR THE THREE MONTHS ENDED JULY 31, 2019 (UNAUDITED)

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity</u>	<u>Non- controlling Interest</u>	<u>Total Equity</u>
	<u>Shares</u>	<u>Par Value</u>					
Balance, April 30, 2019	20,005,075	\$ 200,050	\$183,932,744	\$ (177,589,742)	\$ 6,543,052	\$ (373,387)	\$ 6,169,665
Stock option compensation to employees and directors	-	-	784,246	-	784,246	-	784,246
Stock options and warrants issued to consultants	-	-	46,652	-	46,652	-	46,652
Common stock issued upon exercise of stock options	10,000	100	22,600	-	22,700	-	22,700
Common stock issued in at-the-market offering, net of offering expenses of \$111,275	147,776	1,478	540,464	-	541,942	-	541,942
Net loss	-	-	-	(2,140,028)	(2,140,028)	(26,020)	(2,166,048)
Balance, July 31, 2019	<u>20,162,851</u>	<u>\$ 201,628</u>	<u>\$185,326,706</u>	<u>\$ (179,729,770)</u>	<u>\$ 5,798,564</u>	<u>\$ (399,407)</u>	<u>\$ 5,399,157</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY  
FOR THE NINE MONTHS ENDED JULY 31, 2018 (UNAUDITED)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity	Non- controlling Interest	Total Equity
	Shares	Par Value					
Balance, October 31, 2017	16,602,759	\$ 166,028	\$163,931,079	\$ (156,174,184)	\$ 7,922,923	\$ -	7,922,923
Stock option compensation to employees and directors	-	-	3,598,986	-	3,598,986	-	3,598,986
Stock options and warrants issued to consultants	-	-	254,090	-	254,090	-	254,090
Common stock issued upon exercise of stock options	39,816	398	(398)	-	-	-	-
Restricted stock award compensation to employee pursuant to stock incentive plan	1,500,000	15,000	1,358,940	-	1,373,940	-	1,373,940
Common stock issued to consultants	5,347	53	14,949	-	15,002	-	15,002
Common stock issued in at-the-market offering, net of offering expenses of \$141,140	548,224	5,482	1,780,547	-	1,786,029	-	1,786,029
Issuance of noncontrolling interest in Certainty Therapeutics, Inc	-	-	68,974	-	68,974	(4,318)	64,656
Net loss	-	-	-	(8,693,532)	(8,693,532)	(158,032)	(8,851,564)
Balance, July 31, 2018	<u>18,696,146</u>	<u>\$ 186,961</u>	<u>\$171,007,167</u>	<u>\$ (164,867,716)</u>	<u>\$ 6,326,412</u>	<u>\$ (162,350)</u>	<u>6,164,062</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.



ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY  
FOR THE THREE MONTHS ENDED JULY 31, 2018 (UNAUDITED)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity	Non- controlling Interest	Total Equity
	Shares	Par Value					
Balance, April 30, 2018	16,850,445	\$ 168,504	\$165,288,632	\$ (159,390,790)	\$ 6,066,346	\$ (45,700)	\$ 6,020,646
Stock option compensation to employees and directors	-	-	3,126,454	-	3,126,454	-	3,126,454
Stock options and warrants issued to consultants	-	-	127,939	-	127,939	-	127,939
Restricted stock award compensation to employee pursuant to stock incentive plan	1,500,000	15,000	1,358,940	-	1,373,940	-	1,373,940
Common stock issued in at-the-market offering, net of offering expenses of \$58,198	345,701	3,457	1,105,202	-	1,108,659	-	1,108,659
Net loss	-	-	-	(5,476,926)	(5,476,926)	(116,650)	(5,593,576)
Balance, July 31, 2018	<u>18,696,146</u>	<u>\$ 186,961</u>	<u>\$171,007,167</u>	<u>\$ (164,867,716)</u>	<u>\$ 6,326,412</u>	<u>\$ (162,350)</u>	<u>\$ 6,164,062</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	For the nine months ended	
	July 31,	
	2019	2018
<b>Cash flows from operating activities:</b>		
Reconciliation of net loss to net cash used in operating activities:		
Net loss	\$ (9,707,591)	\$ (8,851,564)
Stock option compensation to employees and directors	2,808,910	3,598,986
Stock options and warrants issued to consultants	139,161	254,090
Restricted stock award compensation to employee pursuant to stock incentive plan	1,954,441	1,373,940
Common stock issued to consultants	-	15,002
Depreciation of property and equipment	32,990	12,414
Amortization of patents	418,750	243,972
Impairment in carrying amount of patent assets	418,750	-
Issuance of noncontrolling interest in Certainty Therapeutics, Inc. expensed as a license fee	-	64,656
Change in operating assets and liabilities:		
Receivables	305,919	(40,710)
Prepaid expenses and other current assets	45,847	(163,211)
Accounts payable	(14,234)	(60,914)
Accrued expenses	192,672	300,888
Net cash used in operating activities	<u>(3,404,385)</u>	<u>(3,252,451)</u>
<b>Cash flows from investing activities:</b>		
Disbursements to acquire short-term investments in certificates of deposit	(2,350,000)	(4,000,000)
Proceeds from maturities of short-term investments in certificates of deposit	2,250,000	4,750,000
Purchase of property and equipment	(175,457)	(31,853)
Net cash (used in) provided by investing activities	<u>(275,457)</u>	<u>718,147</u>
<b>Cash flows from financing activities:</b>		
Net proceeds from sale of common stock in at-the-market offering	4,899,745	1,786,029
Proceeds from sale of common stock pursuant to employee stock purchase plan	18,560	-
Proceeds from exercise of employee stock options	102,500	-
Net cash provided by financing activities	<u>5,020,805</u>	<u>1,786,029</u>
Net increase (decrease) in cash and cash equivalents	1,340,963	(748,275)
Cash and cash equivalents at beginning of period	3,055,890	3,339,374
Cash and cash equivalents at end of period	<u>\$ 4,396,853</u>	<u>\$ 2,591,099</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANIXA BIOSCIENCES, INC. AND SUBSIDIARIES  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

1. BUSINESS AND FUNDING

Description of Business

As used herein, “we,” “us,” “our,” the “Company” or “Anixa” means Anixa Biosciences, Inc. and its consolidated subsidiaries.

Our primary operations involve research and development of cancer therapeutics and diagnostics. Our cancer therapeutics programs consist of development of a vaccine against triple negative breast cancer (“TNBC”) and development of chimeric endocrine receptor T-cell (“CER-T”) technology, a novel form of CAR-T technology, initially focused on treating ovarian cancer. Our cancer diagnostics program consists of development of the artificial intelligence (AI) driven Cchek™ liquid biopsy platform for early cancer detection.

We hold an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Cleveland Clinic Foundation (“Cleveland Clinic”) related to certain breast cancer vaccine technology developed at Cleveland Clinic. We are working in collaboration with Cleveland Clinic to develop a method to vaccinate women against contracting breast cancer, focused specifically on TNBC, the most lethal form of the disease. A specific protein, alpha-lactalbumin, has been identified that is only present during lactation in healthy women, but reappears in many forms of breast cancer, especially TNBC. Animal studies have shown that vaccinating against this protein prevents breast cancer in mice. We are working with researchers at Cleveland Clinic to advance this vaccine toward human clinical testing, and we anticipate filing an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (“FDA”) by the end of the 2019 calendar year.

Our subsidiary, Certainty Therapeutics, Inc. (“Certainty”), is developing immuno-therapy drugs against cancer. Certainty holds an exclusive worldwide, royalty-bearing license to use certain intellectual property owned or controlled by The Wistar Institute (“Wistar”) relating to Wistar’s CER-T technology. We have initially focused on the development of a treatment for ovarian cancer, but we may also pursue applications of the technology for the development of treatments for additional solid tumors. The license agreement requires Certainty to make certain cash and equity payments to Wistar. With respect to Certainty’s equity obligations to Wistar, Certainty issued to Wistar shares of its common stock equal to five percent (5%) of the common stock of Certainty.

Certainty, in collaboration with the H. Lee Moffitt Cancer Center and Research Institute, Inc. (“Moffitt”), is advancing toward human clinical testing of its CER-T technology for treating ovarian cancer. Certainty is working with researchers at Moffitt to complete studies necessary to submit an IND application with the FDA. We anticipate filing the IND with the FDA by the end of the 2019 calendar year, with human clinical trials commencing thereafter, in 2020. The collaboration between Certainty and Moffitt was recently extended through November 2020, so the parties may continue research on Certainty’s CER-T technology.

Our subsidiary, Anixa Diagnostics Corporation (“Anixa Diagnostics”), is developing Cchek™, an AI driven platform of non-invasive blood tests for the early detection of cancer which is based on the body’s immune response to the presence of a malignancy. We have demonstrated the efficacy of Cchek™ with 20 different types of cancer, including: breast, lung, colon, melanoma, ovarian, liver, thyroid, pancreatic, appendiceal, uterine, osteosarcoma, leiomyosarcoma, liposarcoma, vulvar, prostate, bladder, cervical, head and neck, gastric and testicular cancers. Breast, lung, colon and prostate cancers represent the four largest categories of cancer worldwide.

We are currently developing tests for the detection of multiple types of cancer and are working with our development and commercialization partner, ResearchDx, a CLIA-certified laboratory, to launch Cchek™ Prostate Cancer Confirmation as a Laboratory Developed Test during the fourth calendar quarter of 2019.

Over the next several quarters, we expect the development of our breast cancer vaccine, Certainty’s CER-T technology and Anixa Diagnostic’s Cchek™ to be the primary focus of the Company. As part of our legacy operations, the Company remains engaged in limited patent licensing activities in the area of encrypted audio/video conference calling. We do not expect these activities to be a significant part of the Company’s ongoing operations nor do we expect these activities to require material financial resources or attention of senior management.

Over the past several quarters, our revenue was derived from technology licensing and the sale of patented technologies, including revenue from the settlement of litigation. We have not generated any revenue to date from our cancer therapeutics and diagnostics programs. In addition, while we pursue our cancer therapeutics and diagnostics programs, we may also make investments in and form new companies to develop additional emerging technologies.

Funding and Management's Plans

Based on currently available information as of September 5, 2019, we believe that our existing cash, cash equivalents, short-term investments and expected cash flows will be sufficient to fund our activities for the next twelve months. However, our projections of future cash needs and cash flows may differ from actual results. If current cash on hand, cash equivalents, short term investments and cash that may be generated from our business operations are insufficient to continue to operate our business, or if we elect to invest in or acquire a company or companies or new technology or technologies that are synergistic with or complementary to our technologies, we may be required to obtain more working capital. During the nine months ended July 31, 2019, we raised approximately \$4,900,000 through our at-the-market equity offering of 1,208,808 shares of common stock which is currently effective (we can sell an additional 267,302 shares under our current at-the-market equity program) and may remain available for us to use in the future. Further, we have an additional at-the-market equity offering under which we may issue up to \$50 million of common stock, which is currently effective and may remain available to us in the future. We may seek to obtain working capital during our fiscal year 2019 or thereafter through sales of our equity securities or through bank credit facilities or public or private debt from various financial institutions where possible. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we do identify sources for additional funding, the sale of additional equity securities or convertible debt could result in dilution to our stockholders. Additionally, the sale of equity securities or issuance of debt securities may be subject to certain security holder approvals or may result in the downward adjustment of the exercise or conversion price of our outstanding securities. We can give no assurance that we will generate sufficient cash flows in the future to satisfy our liquidity requirements or sustain future operations, or that other sources of funding, such as sales of equity or debt, would be available or would be approved by our security holders, if needed, on favorable terms or at all. If we fail to obtain additional working capital as and when needed, such failure could have a material adverse impact on our business, results of operations and financial condition. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which would significantly harm the business and development of operations.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 8-03 of Regulation S-X. Accordingly, certain information and disclosures required by generally accepted accounting principles in annual financial statements have been omitted or condensed. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related disclosures included in our Annual Report on Form 10-K for the year ended October 31, 2018. The accompanying October 31, 2018 consolidated balance sheet data was derived from the audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America ("US GAAP"). The condensed consolidated financial statements include all adjustments of a normal recurring nature which, in the opinion of management, are necessary for a fair statement of our financial position as of July 31, 2019, and results of operations and cash flows for the interim periods represented. The results of operations for the nine months ended July 31, 2019 are not necessarily indicative of the results to be expected for the entire year.

Noncontrolling Interest

Noncontrolling interest represents Wistar's equity ownership in Certainty and is presented as a component of equity. The following table sets forth the changes in noncontrolling interest for the nine months ended July 31, 2019:

Balance at October 31, 2018	\$	(251,377)
Net loss attributable to noncontrolling interest		(148,030)
Balance at July 31, 2019	\$	<u>(399,407)</u>

Revenue Recognition

Since fiscal 2016 our revenue has been derived solely from technology licensing and the sale of patented technologies. Revenue is recognized upon transfer of control of intellectual property rights and satisfaction of other contractual performance obligations to licensees in an amount that reflects the consideration we expect to receive.

On November 1, 2018 we adopted Accounting Standards Update 2014-09 (“ASU 2014-09”), Revenue from Contracts with Customers. Upon adoption of ASU 2014-09 we are required to make certain judgments and estimates in connection with the accounting for revenue. Such areas may include determining the existence of a contract and identifying each party’s rights and obligations to transfer goods and services, identifying the performance obligations in the contract, determining the transaction price and allocating the transaction price to separate performance obligations, estimating the timing of satisfaction of performance obligations, determining whether a promise to grant a license is distinct from other promised goods or services and evaluating whether a license transfers to a customer at a point in time or over time.

Our revenue arrangements provide for the payment of contractually determined, one-time, paid-up license fees in settlement of litigation and in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. These arrangements typically include some combination of the following: (i) the grant of a non-exclusive, retroactive and future license to manufacture and/or sell products covered by patented technologies owned or controlled by the Company, (ii) a covenant-not-to-sue, (iii) the release of the licensee from certain claims, and (iv) the dismissal of any pending litigation. In such instances, the intellectual property rights granted have been perpetual in nature, extending until the expiration of the related patents. Pursuant to the terms of these agreements, we have no further obligations with respect to the granted intellectual property rights, including no obligation to maintain or upgrade the technology, or provide future support or services. Licensees obtained control of the intellectual property rights they have acquired upon execution of the agreement. As such, the earnings process is complete and revenue is recognized upon the execution of the agreement, when collectability is probable and all other revenue recognition criteria have been met.

Cost of Revenues

Cost of revenues include the costs and expenses incurred in connection with our patent licensing and enforcement activities, including inventor royalties paid to original patent owners, contingent legal fees paid to external counsel, other patent-related legal expenses paid to external counsel, licensing and enforcement related research, consulting and other expenses paid to third-parties and the amortization of patent-related investment costs. These costs are included under the caption “Operating costs and expenses” in the accompanying condensed consolidated statements of operations.

Patents

Our only identifiable intangible assets are patents and patent rights related to our legacy patent licensing operations. We capitalize patent and patent rights acquisition costs and amortize the cost over the estimated economic useful life. No patent acquisition costs were capitalized during the nine months ended July 31, 2019 and 2018. We recorded patent amortization expense of approximately \$419,000 and \$244,000 during the nine-month periods ended July 31, 2019 and 2018, respectively. In evaluating the carrying amount of capitalized patents at January 31, 2019, we determined that based on estimated undiscounted future cash flows a write-down of the carrying amount of approximately \$419,000, to a carrying value of approximately \$168,000, should be recorded as of January 31, 2019. The carrying value of capitalized patents has been amortized to \$- as of July 31, 2019. Our estimates of future cash flows were based on our most recent assessment of the market for potential licensees, as well as the status of ongoing negotiations with potential licensees. While we may be able to generate future cash flows from this patent portfolio, as of July 31, 2019, we cannot reasonably determine an estimate of any such future cash flows.

2. SUBSEQUENT EVENT

On August 21, 2019, the Company entered into a settlement agreement in connection with a putative shareholder derivative complaint filed in the Court of Chancery of the State of Delaware on November 5, 2018. See Note 9 to these condensed consolidation financial statements for additional information. Management reviewed for subsequent events through the date of filing of this Quarterly Report on Form 10-Q and noted no other items requiring disclosure.

3. STOCK BASED COMPENSATION AND WARRANTS

The Company maintains stock equity incentive plans under which the Company grants incentive stock options, non-qualified stock options, stock appreciation rights, stock awards, performance awards, or stock units to employees, directors and consultants.

Stock Option Compensation Expense

The compensation cost for service-based stock options granted to employees and directors is measured at the grant date, based on the fair value of the award using the Black-Scholes pricing model, and is expensed on a straight-line basis over the requisite service period (the vesting period of the stock option). We recorded stock-based compensation expense related to service-based stock options granted to employees and directors of approximately \$2,433,000 and \$1,153,000 during the nine months ended July 31, 2019 and 2018, respectively, and approximately \$784,000 and \$702,000 during the three months ended July 31, 2019 and 2018, respectively.

For stock options granted to employees and directors that vest based on market conditions, such as the trading price of the Company's common stock exceeding certain price targets, we use a Monte Carlo Simulation in estimating the fair value at grant date and recognize compensation cost over the implied service period (median time to vest). On May 8, 2018, we issued market condition options to purchase 1,500,000 shares of common stock, to our Chairman, President and Chief Executive Officer, vesting at target trading prices of \$5.00 to \$8.00 per share before May 31, 2021, with implied service periods of three to seven months. In October 2018, the first tranche of 500,000 shares of market condition options became exercisable upon achieving an average closing price above \$5.00 per share for twenty consecutive trading days. We recorded stock-based compensation expense related to market condition stock options granted to employees of approximately \$376,000 and \$2,446,000 during the nine months ended July 31, 2019 and 2018, respectively, and approximately \$- and \$2,446,000 during the three months ended July 31, 2019 and 2018, respectively.

On November 1, 2018 we adopted Accounting Standards Update 2018-07 ("ASU 2018-07") for stock options granted to consultants. Upon adoption of ASU 2018-07 we estimated the fair value of unvested service-based and performance-based stock options at the date of adoption, using the Black-Scholes pricing model. Subsequent to adoption of ASU 2018-07, future grants to consultants are measured at the grant date, based on the fair value of the award using the Black-Scholes pricing model, consistent with our policy for grants to employees and directors. In prior periods, in accordance with US GAAP, we estimated the fair value of service-based and performance-based stock options granted to consultants at each reporting period using the Black-Scholes pricing model. We recognize the fair value of stock options granted to consultants as consulting expense over the requisite or implied service period of the grant. We recorded stock-based consulting expense related to stock options granted to consultants of approximately \$75,000 and \$197,000 during the nine months ended July 31, 2019 and 2018, respectively, and approximately \$25,000 and \$49,000 during the three months ended July 31, 2019 and 2018, respectively.

Stock Option Activity

During the nine months ended July 31, 2019 and 2018, we granted options to purchase 10,000 shares and 3,897,000 shares of common stock, respectively, to employees, directors and consultants, with exercise prices ranging from \$2.30 to \$3.84 per share, pursuant to the Anixa Biosciences, Inc. 2010 Share Incentive Plan (the "2010 Share Plan") and the Anixa Biosciences, Inc. 2018 Share Plan (the "2018 Share Plan"). During the nine months ended July 31, 2019 and 2018, stock options to purchase 40,000 and 48,600 shares of common stock, respectively, were exercised with aggregate proceeds of approximately \$103,000 and \$-0-, respectively. Under certain circumstances, stock options may be exercised on a cashless basis. During the nine months ended July 31, 2019 and 2018, -0- and 8,784 shares of common stock, respectively, were withheld in connection with cashless exercises of stock options.

Stock Option Plans

As of July 31, 2019, we have three stock option plans: the Anixa Biosciences, Inc. 2003 Share Incentive Plan (the "2003 Share Plan"), the 2010 Share Plan and the 2018 Share Plan, which were adopted by our Board of Directors on April 21, 2003, July 14, 2010 and January 25, 2018, respectively. The 2018 Share Plan was approved by our shareholders on March 29, 2018.

2003 Plan

The 2003 Share Plan provided for the grant of nonqualified stock options, stock appreciation rights, stock awards, performance awards and stock units to employees, directors and consultants. In accordance with the provisions of the 2003 Share Plan, the plan terminated with respect to the ability to grant future options on April 21, 2013. Information regarding the 2003 Share Plan for the nine months ended July 31, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at October 31, 2018	12,000	\$ 2.77	
Exercised	(4,000)	\$ 3.63	
Options outstanding and exercisable at July 31, 2019	<u>8,000</u>	\$ 2.34	\$ 23,694



The following table summarizes information about stock options outstanding and exercisable under the 2003 Share Plan as of July 31, 2019:

Range of Exercise Prices	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$ 0.67 - \$17.00	8,000	0.19	\$ 2.34

Information regarding the 2003 Share Plan for the nine months ended July 31, 2018 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at October 31, 2017	30,600	\$ 3.16	
Exercised	(10,600)	\$ 0.67	
Forfeited	(8,000)	\$ 7.04	
Options outstanding and exercisable at July 31, 2018	<u>12,000</u>	\$ 2.77	\$ 13,054

The following table summarizes information about stock options outstanding and exercisable under the 2003 Share Plan as of July 31, 2018:

Range of Exercise Prices	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$ 0.67 - \$17.00	12,000	.99	\$ 2.77

*2010 Plan*

The 2010 Share Plan provides for the grant of nonqualified stock options, stock appreciation rights, stock awards, performance awards and stock units to employees, directors and consultants. As of July 31, 2019, the 2010 Share Plan had 889,200 shares available for future grants. Information regarding the 2010 Share Plan for the nine months ended July 31, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at October 31, 2018	2,131,868	\$ 2.11	
Granted	10,000	\$ 3.64	
Exercised	(32,000)	\$ 2.27	
Forfeited	(99,200)	\$ 3.78	
Options outstanding at July 31, 2019	<u>2,010,668</u>	\$ 2.03	\$ 5,422,886
Options exercisable at July 31, 2019	<u>1,639,556</u>	\$ 1.92	\$ 4,609,165

The following table summarizes information about stock options outstanding and exercisable under the 2010 Share Plan as of July 31, 2019:

Options Outstanding				Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$ 0.67	938,000	5.94	\$ 0.67	799,388	5.59	\$ 0.67
\$ 2.27 - \$ 3.01	600,134	3.81	\$ 2.58	600,134	3.81	\$ 2.58
\$ 3.46 - \$ 5.75	472,534	8.51	\$ 4.05	240,034	8.19	\$ 4.43

Information regarding the 2010 Share Plan for the nine months ended July 31, 2018 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at October 31, 2017	1,637,246	\$ 1.50	
Granted	475,000	\$ 3.22	
Exercised	(38,000)	\$ 0.67	
Forfeited	(49,800)	\$ 2.15	
Options outstanding at July 31, 2018	2,024,446	\$ 1.90	\$ 2,965,764
Options exercisable at July 31, 2018	1,284,190	\$ 1.73	\$ 2,108,817

The following table summarizes information about stock options outstanding and exercisable under the 2010 Share Plan as of July 31, 2018:

Options Outstanding				Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$ 0.67	943,000	6.94	\$ 0.67	653,142	6.18	\$ 0.67
\$ 2.27 - \$ 3.01	729,712	5.21	\$ 2.61	579,314	5.28	\$ 2.60
\$ 3.46 - \$ 7.00	351,734	8.74	\$ 3.73	51,734	1.46	\$ 5.27

2018 Plan

The 2018 Share Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, stock awards, performance awards and stock units to employees, directors and consultants. As of July 31, 2019, the 2018 Share Plan had 2,008,000 shares available for future grants. Information regarding options outstanding under the 2018 Share Plan for the nine months ended July 31, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at October 31, 2018	3,482,000	\$ 3.73	
Exercised	(4,000)	\$ 3.84	
Forfeited	(8,000)	\$ 3.84	
Options outstanding at July 31, 2019	<u>3,470,000</u>	\$ 3.73	\$ 3,337,300
Options exercisable at July 31, 2019	<u>1,321,111</u>	\$ 3.73	\$ 1,273,443

The following table summarizes information about stock options outstanding and exercisable under the 2018 Share Plan as of July 31, 2019:

Options Outstanding				Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$ 3.70 - \$ 4.61	3,470,000	8.78	\$ 3.73	1,321,111	8.77	\$ 3.73

Information regarding the 2018 Share Plan for the nine months ended July 31, 2018 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at October 31, 2017	-0-		
Granted	3,422,000	\$ 3.71	
Options outstanding at July 31, 2018	<u>3,422,000</u>	\$ 3.71	\$ -0-
Options exercisable at July 31, 2018	<u>167,779</u>	\$ 3.73	\$ -0-

The following table summarizes information about stock options outstanding and exercisable under the 2018 Share Plan as of July 31, 2018:

Options Outstanding				Options Exercisable		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$ 3.70 - \$ 3.84	3,422,000	9.77	\$ 3.71	167,779	9.76	\$ 3.73

*Outside of Share Plans*

In addition to options granted under the 2003 Share Plan, the 2010 Share Plan and the 2018 Share Plan, the Board of Directors approved the grant of stock options to purchase 1,780,000 shares to employees and directors outside of Share Plans. Information regarding stock options outstanding that were granted outside of Share Plans for the nine months ended July 31, 2019 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at October 31, 2018	1,780,000	\$1.58	
Options outstanding and exercisable at July 31, 2019	1,780,000	\$1.58	\$ 5,583,900

The following table summarizes information about stock options outstanding and exercisable that were granted outside of Share Plans as of July 31, 2019:

Range of Exercise Prices	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$ 0.67	1,046,000	3.05	\$ 0.67
\$ 2.58-\$ 5.56	734,000	2.59	\$ 2.88

Information regarding stock options outstanding that were granted outside of Share Plans for the nine months ended July 31, 2018 is as follows:

	Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Options outstanding at October 31, 2017	1,780,000	\$ 1.58	
Options outstanding and exercisable at July 31, 2018	1,780,000	\$ 1.58	\$ 3,206,700

[Table of Contents](#)

The following table summarizes information about stock options outstanding and exercisable that were granted outside of Share Plans as of July 31, 2018:

Range of Exercise Prices	Number Outstanding and Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
\$ 0.67	1,046,000	4.05	\$ 0.67
\$ 2.58-\$ 5.56	734,000	3.59	\$ 2.88

Stock Awards

For stock awards granted to employees, directors and consultants that vest upon grant we recognize expense at the date of grant based on the grant date market price of the underlying common stock. During the nine months ended July 31, 2018, we issued 5,347 shares of common stock that vested upon grant to consultants for services rendered. We recorded consulting expense for the shares of common stock issued to consultants of approximately \$15,000 for the nine months ended July 31, 2018 and \$-0- for the three months ended July 31, 2018. We did not grant any stock awards that vested upon grant during the nine months ended July 31, 2019.

On May 8, 2018, a restricted stock award of 1,500,000 shares of common stock was granted under the 2018 Share Plan to our Chairman, President and Chief Executive Officer. The restricted stock award vests in its entirety upon achievement of a target trading price of \$11.00 per share of the Company's common stock before May 31, 2021. For restricted stock awards vesting upon achievement of a price target of our common stock we use a Monte Carlo Simulation in estimating the fair value at grant date and recognize compensation cost over the implied service period (median time to vest). We recorded stock-based compensation expense related to the restricted stock award of approximately \$1,954,000 and \$1,374,000 during the nine months ended July 31, 2019 and 2018, respectively, and \$-0- and approximately \$1,374,000 during the three months ended July 31, 2019 and 2018, respectively.

Employee Stock Purchase Plan

The Company maintains the Anixa Biosciences, Inc. Employee Stock Purchase Plan which permits eligible employees to purchase shares at not less than 85% of the market value of the Company's common stock on the offering date or the purchase date of the applicable offering period, whichever is lower. The plan was adopted by our Board of Directors on August 13, 2018 and approved by our shareholders on September 27, 2018. During the nine months ended July 31, 2019, employees purchased 5,411 shares at a purchase price of \$3.43 per share pursuant to the plan.

Warrants

During the nine months ended July 31, 2019 we issued a warrant, expiring on November 1, 2023, to purchase 25,000 shares of common stock at \$4.04 per share, vesting over 12 months, to a consultant for investor relations services. We recorded consulting expense of approximately \$64,000 during the nine months ended July 31, 2019 and approximately \$21,000 during the three months ended July 31, 2019, based on the fair value of the warrant recognized on a straight-line basis over the vesting period.

In July 2018 we issued a warrant exercisable at \$3.65 per share vested upon grant to purchase 25,000 shares of common stock to a consultant for investor relations services. We recorded consulting expense of approximately \$57,000 during the three months ended July 31, 2018, based on the fair value of the warrant. This warrant was exercised in October 2018.

As of July 31, 2019, we also had warrants outstanding to purchase 10,000 shares and 10,000 shares of common stock at \$9.25 and \$13.875 per share, respectively, expiring on August 19, 2019 and warrants to purchase 500,000 shares of common stock at \$5.03 per share expiring on November 30, 2021.

#### 4. FAIR VALUE MEASUREMENTS

US GAAP defines fair value and establishes a framework for measuring fair value. We have categorized our financial assets, based on the priority of the inputs to the valuation technique, into a three-level fair value hierarchy as set forth below. If the inputs used to measure the financial instruments fall within different levels of the hierarchy, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Financial assets and liabilities recorded in the accompanying condensed consolidated balance sheets are categorized based on the inputs to the valuation techniques as follows:

Level 1 - Financial assets and liabilities whose values are based on unadjusted quoted prices for identical assets or liabilities in an active market which we have the ability to access at the measurement date.

Level 2 - Financial assets and liabilities whose values are based on quoted market prices in markets where trading occurs infrequently or whose values are based on quoted prices of instruments with similar attributes in active markets.

Level 3 - Financial assets and liabilities whose values are based on prices or valuation techniques that require inputs that are both unobservable and significant to the overall fair value measurement. These inputs reflect management's own assumptions about the assumptions a market participant would use in pricing the asset and liabilities.

The following table presents the hierarchy for our financial assets measured at fair value on a recurring basis as of July 31, 2019:

	Level 1	Level 2	Level 3	Total
Money market funds –				
Cash and cash equivalents	\$ 3,370,661	\$ -	\$ -	\$ 3,370,661
Certificates of deposit –				
Cash and cash equivalents	-	750,000	-	750,000
Short-term investments	-	2,100,000	-	2,100,000
Total financial assets	\$ 3,370,661	\$ 2,850,000	\$ -	\$ 6,220,661

The following table presents the hierarchy for our financial assets measured at fair value on a recurring basis as of October 31, 2018:

	Level 1	Level 2	Level 3	Total
Money market funds –				
Cash and cash equivalents	\$ 2,031,331	\$ -	\$ -	\$ 2,031,331
Certificates of deposit –				
Cash and cash equivalents	-	750,000	-	750,000
Short-term investments	-	2,000,000	-	2,000,000
Total financial assets	<u>\$ 2,031,331</u>	<u>\$ 2,750,000</u>	<u>\$ -</u>	<u>\$ 4,781,331</u>

Our non-financial assets that are measured on a non-recurring basis include our patents and property and equipment which are measured using fair value techniques whenever events or changes in circumstances indicate a condition of impairment exists. The estimated fair value of prepaid expenses, accounts payable and accrued expenses approximates their individual carrying amounts due to the short-term nature of these measurements. Cash and cash equivalents are stated at carrying value which approximates fair value.

#### 5. ACCRUED EXPENSES

Accrued expenses consist of the following as of:

	July 31, 2019	October 31, 2018
Payroll and related expenses	\$ 64,627	\$ 62,965
Accrued royalty and contingent legal fees	449,691	366,670
Accrued collaborative research and license expenses	351,994	187,500
Accrued other	9,459	65,964
	<u>\$ 875,771</u>	<u>\$ 683,099</u>

#### 6. NET LOSS PER SHARE OF COMMON STOCK

Basic net loss per common share (“Basic EPS”) is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per common share (“Diluted EPS”) is computed by dividing net loss by the weighted average number of common shares and dilutive common share equivalents and convertible securities then outstanding. Diluted EPS for all periods presented is the same as Basic EPS, as the inclusion of the effect of common share equivalents then outstanding would be anti-dilutive. For this reason, excluded from the calculation of Diluted EPS for the nine and three months ended July 31, 2019 and 2018, were stock options to purchase 7,268,668 and 7,238,446 shares, respectively, and warrants to purchase 545,000 and 854,400 shares, respectively.

7. EFFECT OF RECENTLY ADOPTED AND ISSUED PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2014-09 ("ASU 2014-09"), Revenue from Contracts with Customers. This amendment updates addressing revenue from contracts with customers, which clarifies existing accounting literature relating to how and when a company recognizes revenue. Under the standard, a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. The Company adopted ASU 2014-09 on November 1, 2018. The adoption of ASU 2014-09 did not have a material impact on our consolidated financial statements, other than required additional disclosure of accounting policies. See Note 1 regarding our revenue recognition policy.

In February 2016, the FASB issued Accounting Standards Update 2016-02 ("ASU 2016-02") which requires lessees to recognize most leases on the balance sheet. This is expected to increase both reported assets and liabilities. The new lease standard does not substantially change lessor accounting. For public companies, the standard will be effective for the first interim reporting period within annual periods beginning after December 15, 2018, although early adoption is permitted. Lessees and lessors will be required to apply the new standard at the beginning of the earliest period presented in the financial statements in which they first apply the new guidance, using a modified retrospective transition method. The requirements of this standard include a significant increase in required disclosures. We began a detailed assessment of the impact that this guidance will have on our consolidated financial statements and related disclosures, and our analysis is currently ongoing.



8. INCOME TAXES

We file Federal, New York and California state income tax returns. Due to net operating losses, the statute of limitations for Federal and New York State income tax returns remains open to examination by taxing authorities since the fiscal year ended October 31, 1999. We account for interest and penalties related to income tax matters, if any, in general and administrative expenses. There are no unrecognized income tax benefits as of July 31, 2019 and October 31, 2018.

We recognize deferred tax assets and liabilities for the estimated future tax effects of events that have been recognized in our financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is established, when necessary, to reduce deferred tax assets to the amount expected to be realized. We have substantial net operating loss carryforwards for Federal, New York State and California income tax returns. These net operating loss carryforwards could be subject to limitations under Internal Revenue Code section 382. Management has not performed an analysis of the potential limitations. We have provided a full valuation allowance against our deferred tax asset due to our historical pre-tax losses and the uncertainty regarding the realizability of these deferred tax assets.

9. COMMITMENT AND CONTINGENCES

Litigation Matters

Other than below and lawsuits we have historically brought to enforce our patent rights, we are not a party to any material pending legal proceedings other than that which arise in the ordinary course of business. We believe that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, have a material adverse effect on our financial position or results of operations.

On November 5, 2018, a putative shareholder derivative complaint was filed in the Court of Chancery of the State of Delaware, captioned Howland v. Kumar et al., C.A. No. 2018-0804-KSJM (the "Derivative Action"), that alleged claims for breach of fiduciary duty and unjust enrichment. The Derivative Action named as defendants certain of the Company's current and former officers and directors (the "Individual Defendants"), and the Company was named solely as a nominal defendant. On August 21, 2019, the Company entered into a settlement pursuant to which the Company agreed to certain changes in its corporate governance policies and to reprice certain stock options that were repriced on September 6, 2017 to \$0.67 to the option price immediately prior to that repricing. The Company also agreed to pay certain legal fees, with such fees to be paid from the Company's D&O insurance. As a result of this settlement, all of the claims asserted in the Derivative Action will be dismissed. The Individual Defendants have denied, and continue to deny, any and all allegations of wrongdoing or liability asserted in the Derivative Action. The Individual Defendants have further asserted, and continue to assert, that at all relevant times, they acted in good faith and in a manner that they reasonably believed to be in the best interests of the Company and its stockholders. The Individual Defendants have entered into the settlement solely to eliminate the uncertainty, distraction, disruption, burden, risk, and expense of further litigation.

10. SEGMENT INFORMATION

We follow the accounting guidance of ASC 280 “Segment Reporting” (“ASC 280”). Reportable operating segments are determined based on the management approach. The management approach, as defined by ASC 280, is based on the way that the chief operating decision-maker organizes the segments within an enterprise for making operating decisions and assessing performance. While our results of operations are primarily reviewed on a consolidated basis, the chief operating decision-maker manages the enterprise in three reportable segments, each with different operating and potential revenue generating characteristics: (i) Cancer Diagnostics, (ii) Cancer Therapeutics and (iii) our legacy patent licensing activities. The following represents selected financial information for our segments for the nine and three months ended July 31, 2019 and 2018 and as of July 31, 2019 and October 31, 2018:

	For the Nine Months Ended	
	July 31,	
	2019	2018
Net loss:		
Cancer Diagnostics	\$ (4,024,785)	\$ (3,783,854)
Cancer Therapeutics	(4,807,668)	(4,583,070)
Patent licensing	(875,138)	(484,640)
Total	<u>\$ (9,707,591)</u>	<u>\$ (8,851,564)</u>
Operating costs and expenses excluding non-cash share based compensation expense:		
Cancer Diagnostics	\$ 1,953,760	\$ 1,692,865
Cancer Therapeutics	2,084,694	1,807,515
Patent licensing	1,070,408	1,266,448
Total	<u>\$ 5,108,862</u>	<u>\$ 4,766,828</u>
Operating costs and expenses excluding non-cash share based compensation expense	\$ 5,108,862	\$ 4,766,828
Plus non-cash share-based compensation expense	4,902,512	5,227,016
Total operating costs and expenses	<u>\$ 10,011,374</u>	<u>\$ 9,993,844</u>
	For the Three Months Ended	
	July 31,	
	2019	2018
Net loss:		
Cancer Diagnostics	\$ (917,363)	\$ (2,359,568)
Cancer Therapeutics	(1,203,468)	(2,901,708)
Patent licensing	(45,217)	(332,300)
Total	<u>\$ (2,166,048)</u>	<u>\$ (5,593,576)</u>
Operating costs and expenses excluding non-cash share based compensation expense:		
Cancer Diagnostics	\$ 507,356	\$ 569,512
Cancer Therapeutics	801,704	359,006
Patent licensing	44,454	411,453
Total	<u>\$ 1,353,514</u>	<u>\$ 1,339,971</u>
Operating costs and expenses excluding non-cash share based compensation expense	\$ 1,353,514	\$ 1,339,971
Plus non-cash share-based compensation expense	830,898	4,628,333
Total operating costs and expenses	<u>\$ 2,184,412</u>	<u>\$ 5,968,304</u>
	July 31,	October 31,
	2019	2018
Total assets:		
Cancer Diagnostics	\$ 3,201,233	\$ 2,545,803
Cancer Therapeutics	3,279,496	2,157,359
Patent licensing	361,977	1,745,380
Total	<u>\$ 6,842,706</u>	<u>\$ 6,448,542</u>

Operating costs and expenses excluding non-cash share-based compensation expense is the measurement the chief operating decision-maker uses in managing the enterprise.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

**GENERAL**

We discuss the description of our business in the Notes to our Condensed Consolidated Financial Statements.

**RESULTS OF OPERATIONS**

**Nine months ended July 31, 2019 compared with nine months ended July 31, 2018**

***Revenue***

For the nine months ended July 31, 2019, we recorded revenue of \$250,000 from one license agreement. For the nine months ended July 31, 2018, we recorded revenue of \$1,112,500 from two license agreements. These license agreements each provided for a one-time, non-recurring, lump sum payment in exchange for non-exclusive retroactive and future licenses, and covenants not to sue. Pursuant to the terms of these agreements, we have no further obligations with respect to the granted intellectual property rights, including no obligation to maintain or upgrade the technology, or provide future support or services. Accordingly, the earnings process from these licenses was complete and 100% of the revenue was recognized upon execution of the license agreement. As discussed in Note 1 to our consolidated financial statements, as part of our legacy operations, the Company remains engaged in limited patent licensing activities which we do not expect to be a significant part of our ongoing operations or revenue.

***Inventor Royalties, Contingent Legal Fees and Litigation and Licensing Expenses Related to Patent Assertion***

Inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion activities decreased by approximately \$601,000 to approximately \$166,000 in the nine months ended July 31, 2019, compared to approximately \$767,000 in the comparable prior year. The decrease was primarily due to the decrease in related revenues. Inventor royalties and contingent legal fees are expensed in the period that the related revenues are recognized. Litigation and licensing expenses related to patent assertion, other than contingent legal fees, are expensed in the period incurred.

***Amortization of Patents***

Amortization of patents increased by approximately \$175,000 to approximately \$419,000 in the nine months ended July 31, 2019, from approximately \$244,000 in the nine months ended July 31, 2018. We capitalize patent and patent rights acquisition costs and amortize the cost over the estimated economic useful life. The increase in amortization of patents was due to a reduction in the estimated economic useful life of capitalized patents.

### ***Research and Development Expenses***

Research and development expenses are related to the development of our cancer diagnostics and therapeutics programs and increased by approximately \$222,000 to approximately \$4,602,000 in the nine months ended July 31, 2019, from approximately \$4,380,000 in the nine months ended July 31, 2018. The increase in research and development expenses was primarily due to an increase in employee stock award compensation expense of approximately \$481,000, an increase in outside research and development expense, excluding license expense, primarily related to Certainty's collaboration agreement with Moffitt and Anixa Diagnostics' agreement with our development partner, ResearchDx, of approximately \$356,000 and an increase in employee compensation and related costs, other than equity-based compensation, of approximately \$95,000, offset by a decrease of approximately \$562,000 in employee stock option compensation expense and a decrease in license fees of approximately \$190,000. License fees in fiscal year 2019 are related to our license with Cleveland Clinic. License fees in fiscal year 2018 are related to our license with Wistar.

### ***General and Administrative Expenses***

General and administrative expenses decreased by approximately \$198,000 to approximately \$4,405,000 in the nine months ended July 31, 2019, from approximately \$4,603,000 in the nine months ended July 31, 2018. The decrease in general and administrative expenses was principally due to a decrease in employee stock option compensation expense of approximately \$228,000, a decrease in consultant stock option expense of approximately \$105,000 and a decrease in investor and public relations expense of approximately \$86,000, offset by a patent expense reimbursement to Cleveland Clinic of approximately \$164,000 and an increase in employee stock award compensation expense of approximately \$99,000.

### ***Impairment in Carrying Amount of Patent Assets***

The impairment in carrying amount of patent assets related to our legacy patent licensing activities of approximately \$419,000 in the nine months ended July 31, 2019 resulted from the write down of the value of our patent assets to the estimated undiscounted future cash flows we anticipated receiving from the patent assets as of January 31, 2019 of approximately \$168,000. Our estimates of future cash flows were based on our most recent assessment of the market for potential licensees, as well as the status of ongoing negotiations with potential licensees.

### ***Interest Income***

Interest income increased by approximately \$24,000 to approximately \$54,000 in the nine months ended July 31, 2019, from approximately \$30,000 in the comparable prior year period as a result of greater amounts of cash, cash equivalents and short-term investments in certificates of deposit.

### ***Net Loss Attributable to Noncontrolling Interest***

The net loss attributable to noncontrolling interest, representing Wistar's 5% ownership interest in Certainty's net loss, decreased by approximately \$10,000 to approximately \$148,000 in the nine months ended July 31, 2019, from approximately \$158,000 in the nine months ended July 31, 2018, as Certainty's net loss decreased. The decrease in Certainty's net loss was primarily due to decreases in employee stock option compensation expense and employee stock award compensation expense.

**Three months ended July 31, 2019 compared with three months ended July 31, 2018**

***Revenue***

We had no revenue during the three months ended July 31, 2019. For the three months ended July 31, 2018, we recorded revenue of \$362,500 from one license agreement. The license agreement provided for a one-time, non-recurring, lump sum payment in exchange for non-exclusive retroactive and future licenses, and covenants not to sue. Pursuant to the terms of the agreement, we have no further obligations with respect to the granted intellectual property rights, including no obligation to maintain or upgrade the technology, or provide future support or services. Accordingly, the earnings process from these licenses was complete and 100% of the revenue was recognized upon execution of the license agreement. As discussed in Note 1 to our consolidated financial statements, as part of our legacy operations, the Company remains engaged in limited patent licensing activities which we do not expect to be a significant part of our ongoing operations or revenue.

***Inventor Royalties, Contingent Legal Fees and Litigation and Licensing Expenses Related to Patent Assertion***

We had no inventor royalties, contingent legal fees, litigation and licensing expenses related to patent assertion activities during the three months ended July 31, 2019, compared to approximately \$241,000 in the comparable prior year. Inventor royalties and contingent legal fees are expensed in the period that the related revenues are recognized. Litigation and licensing expenses related to patent assertion, other than contingent legal fees, are expensed in the period incurred.

***Amortization of Patents***

Amortization of patents decreased by approximately \$39,000 to approximately \$42,000 in the three months ended July 31, 2019, from approximately \$81,000 in the three months ended July 31, 2018. We capitalize patent and patent rights acquisition costs and amortize the cost over the estimated economic useful life. The decrease in amortization of patents was due to a reduction in the carrying value of the patents.

***Research and Development Expenses***

Research and development expenses are related to the development of our cancer diagnostics and therapeutics programs and decreased by approximately \$1,856,000 to approximately \$1,086,000 in the three months ended July 31, 2019, from approximately \$2,942,000 in the three months ended July 31, 2018. The decrease in research and development expenses was primarily due to a decrease in employee stock option compensation expense of approximately \$1,384,000 and a decrease in employee stock award compensation expense of approximately \$769,000, offset by an increase in outside research and development expense, excluding license expense, primarily related to Certainty's collaboration agreement with Moffitt and Anixa Diagnostics' agreement with our development partner, ResearchDx, of approximately \$149,000 and approximately \$100,000 of license fees paid to Cleveland Clinic.

***General and Administrative Expenses***

General and administrative expenses decreased by approximately \$1,647,000 to approximately \$1,057,000 in the three months ended July 31, 2019, from approximately \$2,704,000 in the three months ended July 31, 2018. The decrease in general and administrative expenses was principally due to a decrease in employee stock option compensation expense of approximately \$980,000, a decrease in employee stock award compensation expense of approximately \$605,000, a decrease in legal and accounting fees of approximately \$147,000 primarily related to a putative shareholder derivative complaint (see Note 9 to our condensed consolidated financial statements) and a decrease in investor and public relations expense of approximately \$102,000, offset by a patent expense reimbursement to Cleveland Clinic of approximately \$164,000.

***Interest Income***

Interest income increased by approximately \$6,000 to approximately \$18,000 in the three months ended July 31, 2019, from approximately \$12,000 in the comparable prior year period as a result of greater amounts of cash, cash equivalents and short-term investments in certificates of deposit.

***Net Loss Attributable to Noncontrolling Interest***

The net loss attributable to noncontrolling interest, representing Wistar's 5% ownership interest in Certainty's net loss, decreased by approximately \$91,000 to approximately \$26,000 in the three months ended July 31, 2019, from approximately \$117,000 in the three months ended July 31, 2018, as Certainty's net loss decreased. The decrease in Certainty's net loss was primarily due to decreases in employee stock option compensation expense and employee stock award compensation expense.

**LIQUIDITY AND CAPITAL RESOURCES**

Our primary sources of liquidity are cash, cash equivalents and short-term investments.

Based on currently available information as of September 5, 2019, we believe that our existing cash, cash equivalents, short-term investments and expected cash flows will be sufficient to fund our activities for the next twelve months. However, our projections of future cash needs and cash flows may differ from actual results. If current cash on hand, cash equivalents, short term investments and cash that may be generated from our business operations are insufficient to continue to operate our business, or if we elect to invest in or acquire a company or companies or new technology or technologies that are synergistic with or complementary to our technologies, we may be required to obtain more working capital. During the nine months ended July 31, 2019, we raised approximately \$4,900,000 through our at-the-market equity offering of 1,208,808 shares of common stock which is currently effective (we can sell an additional 267,302 shares under our current at-the-market equity program) and may remain available for us to use in the future. Further, we have an additional at-the-market equity offering under which we may issue up to \$50 million of common stock, which is currently effective and may remain available to us in the future. We may seek to obtain working capital during our fiscal year 2019 or thereafter through sales of our equity securities (including through the commencement of another at-the-market equity offering) or through bank credit facilities or public or private debt from various financial institutions where possible. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we do identify sources for additional funding, the sale of additional equity securities or convertible debt could result in dilution to our stockholders. Additionally, the sale of equity securities or issuance of debt securities may be subject to certain security holder approvals or may result in the downward adjustment of the exercise or conversion price of our outstanding securities. We can give no assurance that we will generate sufficient cash flows in the future to satisfy our liquidity requirements or sustain future operations, or that other sources of funding, such as sales of equity or debt, would be available or would be approved by our security holders, if needed, on favorable terms or at all. If we fail to obtain additional working capital as and when needed, such failure could have a material adverse impact on our business, results of operations and financial condition. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which would significantly harm the business and development of operations

During the nine months ended July 31, 2019, cash used in operating activities was approximately \$3,404,000. Cash used in investing activities was approximately \$275,000, resulting from the purchase of certificates of deposit totaling \$2,350,000 and the purchase of property and equipment of approximately \$175,000, which was offset by the proceeds on maturities of certificates of deposit totaling \$2,250,000. Cash provided by financing activities was approximately \$5,021,000, resulting from the sale of 1,208,808 shares of common stock in our at-the-market equity offering over the past nine months of approximately \$4,900,000 (which is ongoing), the proceeds from sale of common stock pursuant to employee stock purchase plan of approximately \$19,000 and the proceeds from exercise of stock options of approximately \$103,000. As a result, our cash, cash equivalents, and short-term investments at July 31, 2019 increased approximately \$1,441,000 to approximately \$6,497,000 from approximately \$5,056,000 at the end of fiscal year 2018.

#### **CRITICAL ACCOUNTING POLICIES**

The Company's condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America. In preparing these financial statements, we make assumptions, judgments and estimates that can have a significant impact on amounts reported in our condensed consolidated financial statements. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates and make changes accordingly.

We believe that, of the significant accounting policies discussed in Note 2 to our consolidated financial statements in our Annual Report on Form 10-K for the fiscal year ended October 31, 2018, the following accounting policies require our most difficult, subjective or complex judgments:

Revenue Recognition; and  
Stock-Based Compensation.

### **Revenue Recognition**

Our revenue has been derived solely from technology licensing and the sale of patented technologies. Revenue is recognized upon transfer of control of intellectual property rights and satisfaction of other contractual performance obligations to licensees in an amount that reflects the consideration we expect to receive.

On November 1, 2018 we adopted Accounting Standards Update 2014-09 (“ASU 2014-09”), Revenue from Contracts with Customers. Upon adoption of ASU 2014-09 we are required to make certain judgments and estimates in connection with the accounting for revenue. Such areas may include determining the existence of a contract and identifying each party’s rights and obligations to transfer goods and services, identifying the performance obligations in the contract, determining the transaction price and allocating the transaction price to separate performance obligations, estimating the timing of satisfaction of performance obligations, determining whether a promise to grant a license is distinct from other promised goods or services and evaluating whether a license transfers to a customer at a point in time or over time.

Our revenue arrangements provide for the payment of contractually determined, one-time, paid-up license fees in settlement of litigation and in consideration for the grant of certain intellectual property rights for patented technologies owned or controlled by the Company. These arrangements typically include some combination of the following: (i) the grant of a non-exclusive, retroactive and future license to manufacture and/or sell products covered by patented technologies owned or controlled by the Company, (ii) a covenant-not-to-sue, (iii) the release of the licensee from certain claims, and (iv) the dismissal of any pending litigation. In such instances, the intellectual property rights granted have been perpetual in nature, extending until the expiration of the related patents. Pursuant to the terms of these agreements, we have no further obligations with respect to the granted intellectual property rights, including no obligation to maintain or upgrade the technology, or provide future support or services. Licensees obtained control of the intellectual property rights they have acquired upon execution of the agreement. As such, the earnings process is complete and revenue is recognized upon the execution of the agreement, when collectability is probable and all other revenue recognition criteria have been met.

### **Stock-Based Compensation**

The compensation cost for service-based stock options granted to employees and directors is measured at the grant date, based on the fair value of the award using the Black-Scholes pricing model, and is expensed on a straight-line basis over the requisite service period (the vesting period of the stock option) which is one to four years. For employee options vesting if the trading price of the Company’s common stock exceeds certain price targets we use a Monte Carlo Simulation in estimating the fair value at grant date and recognize compensation cost over the implied service period.



For stock awards granted to employees and directors that vest at date of grant we recognize expense based on the grant date market price of the underlying common stock. For restricted stock awards vesting upon achievement of a price target of our common stock we use a Monte Carlo Simulation in estimating the fair value at grant date and recognize compensation cost over the implied service period (median time to vest).

On November 1, 2018 we adopted Accounting Standards Update 2018-07 (“ASU 2018-027”) for stock-based compensation to non-employees. Upon adoption of ASU 2018-07 we estimated the fair value of unvested awards at the date of adoption, using the Black-Scholes pricing model. Future grants to consultants will be measured at the grant date, based on the fair value of the award using the Black-Scholes pricing model, consistent with our policy for grants to employees and directors.

The Black-Scholes pricing model and the Monte Carlo Simulation we use to estimate fair values requires valuation assumptions of expected term, expected volatility, risk-free interest rates and expected dividend yield. The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. For employees we use the simplified method, which is a weighted average of the vesting term and contractual term, to determine expected term. The simplified method was adopted since we do not believe that historical experience is representative of future performance because of the impact of the changes in our operations and the change in terms from historical options. For consultants we use the contract term for expected term. We estimate the expected volatility of our shares of common stock based upon the historical volatility of our share price over a period of time equal to the expected term of the grants. We estimate the risk-free interest rate based on the implied yield available on the applicable grant date of a U.S. Treasury note with a term equal to the expected term of the underlying grants. We made the dividend yield assumption based on our history of not paying dividends and our expectation not to pay dividends in the future.

We will reconsider use of the Black-Scholes pricing model and Monte Carlo Simulation if additional information becomes available in the future that indicates other models would be more appropriate. If factors change and we employ different assumptions in future periods, the compensation expense that we record may differ significantly from what we have recorded in the current period.

#### **EFFECT OF RECENTLY ISSUED PRONOUNCEMENTS**

We discuss the effect of recently issued pronouncements in the Notes to our Condensed Consolidated Financial Statements.

## **FORWARD-LOOKING STATEMENTS**

Information included in this Quarterly Report on Form 10-Q (this “Report”) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Forward-looking statements are not statements of historical facts, but rather reflect our current expectations concerning future events and results. We generally use the words “believes,” “expects,” “intends,” “plans,” “anticipates,” “likely,” “will” and similar expressions to identify forward-looking statements. Such forward-looking statements, including those concerning our expectations, involve risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. These risks, uncertainties and factors include, but are not limited to, those factors set forth in our Annual Report on Form 10-K for the fiscal year ended October 31, 2018 and the condensed consolidated financial statements included in this Report. Except as required by applicable law, including the securities laws of the United States, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are cautioned not to unduly rely on such forward-looking statements when evaluating the information presented in this Report.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

As of July 31, 2019, we had investments in short-term, fixed rate and highly liquid instruments that have historically been reinvested when they mature throughout the year. Although our existing instruments are not considered at risk with respect to changes in interest rates or markets for these instruments, our rate of return on these securities could be affected at the time of reinvestment, if any.

### **Item 4. Controls and Procedures.**

We carried out an evaluation, under the supervision and with the participation of our management including our President and Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13-15(b) of the Exchange Act. Based upon that evaluation, our President and Chief Executive Officer and our Chief Operating Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of the end of the period covered by this report.

There was no change in our internal control over financial reporting during the third quarter of fiscal year 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings.**

Other than as described below and lawsuits we have historically brought to enforce our patent rights we are not a party to any material pending legal proceedings other than that which arise in the ordinary course of business. We believe that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, have a material adverse effect on our financial position or results of operations.

On November 5, 2018, a putative shareholder derivative complaint was filed in the Court of Chancery of the State of Delaware, captioned Howland v. Kumar et al., C.A. No. 2018-0804-KSJM (the “Derivative Action”), that alleged claims for breach of fiduciary duty and unjust enrichment. The Derivative Action named as defendants certain of the Company’s current and former officers and directors (the “Individual Defendants”), and the Company was named solely as a nominal defendant. On August 21, 2019, the Company entered into a settlement pursuant to which the Company agreed to certain changes in its corporate governance policies and to reprice certain stock options that were repriced on September 6, 2017 to \$0.67 to the option price immediately prior to that repricing. The Company also agreed to pay certain legal fees, with such fees to be paid from the Company’s D&O insurance. As a result of this settlement, all of the claims asserted in the Derivative Action will be dismissed. The Individual Defendants have denied, and continue to deny, any and all allegations of wrongdoing or liability asserted in the Derivative Action. The Individual Defendants have further asserted, and continue to assert, that at all relevant times, they acted in good faith and in a manner that they reasonably believed to be in the best interests of the Company and its stockholders. The Individual Defendants have entered into the settlement solely to eliminate the uncertainty, distraction, disruption, burden, risk, and expense of further litigation.

**Item 1A. Risk Factors.**

There have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the fiscal year ended October 31, 2018.

**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.**

- 10.1 [Exclusive License Agreement, dated July 8, 2019, between Anixa Biosciences, Inc. and The Cleveland Clinic Foundation. \(Filed herewith.\) \(Certain information has been redacted in the marked portions of the exhibit.\)](#)
- 10.2 [Amendment 1 to the Collaboration Agreement between Certainty Therapeutics, Inc. and H. Lee Moffitt Cancer Center and Research Institute, Inc. \(Filed herewith.\)](#)
- 31.1 [Certification of Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated September 6, 2019.](#)
- 31.2 [Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated September 6, 2019.](#)
- 32.1 [Statement of Chief Executive Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated September 6, 2019.](#)
- 32.2 [Statement of Chief Financial Officer, pursuant to Section 1350 of Title 18 of the United States Code, dated September 6, 2019.](#)

**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.

ANIXA BIOSCIENCES, INC.

By:/s/ Dr. Amit Kumar  
Dr. Amit Kumar  
Chairman, President and  
Chief Executive Officer  
(Principal Executive Officer)

September 6, 2019

By:/s/ Michael J. Catelani  
Michael J. Catelani  
Chief Operating Officer and  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)

September 6, 2019

Redactions with respect to certain portions hereof denoted with “\*\*\*\*”

**EXCLUSIVE LICENSE AGREEMENT**

**between**

**THE CLEVELAND CLINIC FOUNDATION**

**and**

**ANIXA BIOSCIENCES, INC.**

**dated as of**

**July 8, 2019**

---

**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

**EXCLUSIVE LICENSE AGREEMENT**

This Exclusive License Agreement (this “**Agreement**”) is made and entered into effective as of July 8, 2019 (the “**Effective Date**”), by and between The Cleveland Clinic Foundation, a nonprofit Ohio corporation (“**Licensor**”), and Anixa Biosciences, Inc., a Delaware corporation (“**Licensee**”).

**RECITALS:**

WHEREAS, Licensor owns certain patents and/or patent applications pertaining to the use of vaccines for the treatment or prevention of Triple Negative Breast Cancer (TNBC) and other breast cancers, which express the a-lactalbumin protein, developed by Vincent K. Tuohy (who is an Inventor as defined below) that it believes should be developed and commercialized for the greater public good; and

WHEREAS, Licensor desires to grant to Licensee an exclusive license under such patents and/or patent applications in order to develop and commercialize such technology, and Licensee desires such license and agrees to use commercially reasonable efforts to develop and commercialize such technology, in each case subject to the terms, conditions and other provisions contained herein.

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

Article 1  
DEFINITIONS

1.1 Defined Terms. In addition to such terms as are defined elsewhere in this Agreement, the capitalized terms in this Agreement shall have the following meanings:

“**Action**” has the meaning set forth in Section 10.1.1.

“**Affiliate**” as to any Person, means any other Person that, directly or indirectly through one or more intermediaries, is in control of, is controlled by, or is under common control with, such Person. For purposes of this definition, "control" of a Person means the power, directly or indirectly, either to (a) vote 50% or more of the securities having ordinary voting power for the election of directors (or persons performing similar functions) of such Person or (b) direct or cause the direction of the management and policies of such Person, whether by contract or otherwise.

“**Agent**” has the meaning set forth in Section 23.3.

“**Agreement**” has the meaning set forth in the Preamble.

“**Annual Update**” has the meaning set forth in Section 4.2(b).

“**Bankruptcy Code**” means Title 11 of the United States Code, as amended from time to time, or any similar federal or state law for the relief of debtors.

“**Change in Control**” of any Person means (a) a merger or consolidation of such Person, (b) a transaction or series of related transactions in which any Person or group of persons within the meaning of § 13(d)(3) of the Securities Exchange Act of 1934, becomes the beneficial owner, directly or indirectly, of fifty percent (50%) or more of the combined voting power of the outstanding securities of such Person, or (c) the sale or other transfer to a third party of all or substantially all of such Person’s assets related to the subject matter of this Agreement.

---

**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

“**Confidential Information**” means all non-public, confidential or proprietary information of a party, or its Affiliates or Representatives, that is disclosed directly or indirectly from or on behalf of the Disclosing Party to the Receiving Party, whether in oral, written, electronic or other form or media, whether or not such information is marked, designated or otherwise identified as "confidential" and that, due to the nature of its subject matter or circumstances surrounding its disclosure, would reasonably be understood to be confidential or proprietary, including, without limitation, the Licensed Know-how and the terms and existence of this Agreement.

Confidential Information does not include information that the Receiving Party can demonstrate by documentation or other evidence (i) was already known to the Receiving Party without restriction on use or disclosure prior to the receipt of such information directly or indirectly from or on behalf of the Disclosing Party; (ii) was independently developed by the Receiving Party without use of or reference to the Disclosing Party's Confidential Information; (iii) is or becomes generally known to the public or otherwise becomes publicly available, other than through a breach of this Agreement by the Receiving Party; or (iv) is or was made available to the Receiving Party on a non-confidential basis by a third party having the lawful right to do so without breaching any obligation of confidentiality to the Disclosing Party.

“**Cure Period**” has the meaning set forth in [Section 4.1\(b\)](#).

“**Debarred**” has the meaning set forth in [Section 23.3](#).

“**Debtor Relief Law**” means the Bankruptcy Code and all other liquidation, bankruptcy, assignment for the benefit of creditors, conservatorship, moratorium, receivership, insolvency, rearrangement, reorganization or similar debtor relief laws of the US or other applicable jurisdictions in effect from time to time.

“**Declaring Party**” has the meaning set forth in [Section 9.2.2](#).

“**Default**” means any of the events specified in [Section 7.2](#), [Section 7.4](#), or anywhere else in this Agreement, which results in (a) Licensor having the right to terminate this Agreement or (b) automatic termination of this Agreement.

“**Development Plan**” means the initial plan to be attached hereto as [Exhibit A](#) pursuant to [Section 5.7](#), setting forth the strategy and schedule for Licensee's research, development and testing of Licensed Products, including the estimated dates of initiation and completion of material development activities (to be performed by or on behalf of Licensee or Licensor) leading to Regulatory Approval and commercial sale of Licensed Products, and thereafter any updates to the development plan as provided by Licensee pursuant to [Section 4.2](#).

“**Development Report**” means a written account of Licensee's progress under the Development Plan including the information specified in [Exhibit C](#) to this Agreement.

“**Disclosing Party**” has the meaning set forth in [Section 8.1](#).

“**Dispute**” has the meaning set forth in [Section 9.2.1](#).

“**Earned Know-how Royalty**” has the meaning set forth in [Section 3.2\(b\)](#).



**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

“**Earned Patent Royalty**” has the meaning set forth in Section 3.2(a).

“**Earned Royalties**” means, collectively, the Earned Patent Royalty and the Earned Know-how Royalty.

“**Effective Date**” has the meaning set forth in the Preamble.

The expression “**expiration**” and “**expire**”, when referring to a claim in a Licensed Patent means any expiration, revocation, invalidation or other termination of a Licensed Patent incorporating the pending, issued or enforceable claim.

“**FDA**” has the meaning set forth in the definition of Regulatory Authority.

“**Field 1**” means vaccines for the prevention of Triple Negative Breast Cancer (TNBC) and other breast cancers, which express the a-lactalbumin protein.

“**Field 2**” means vaccines for the therapeutic treatment of Triple Negative Breast Cancer (TNBC) and other breast cancers, which express the a-lactalbumin protein.

“**Fields**” means, collectively, Field 1 and Field 2.

“**First Commercial Sale**” means the first arms-length, non-clinical trial-related sale of a Licensed Product.

“**Force Majeure Event**” has the meaning set forth in Section 4.1(b).

“**GAAP**” means generally accepted accounting principles in the United States of America as in effect from time to time.

“**Governmental Authority**” means the government of any nation or any political subdivision thereof, whether at the national, state, territorial, provincial, municipal or any other level, and any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of, or pertaining to, government.

“**Indemnitee**” has the meaning set forth in Section 10.1.1.

“**Infringement Notice**” has the meaning set forth in Section 6.4.1.

“**Inventor**” means each person listed as an inventor on any Licensed Patent.

“**Issue Fee**” has the meaning set forth in Section 3.1.

“**Law**” means any statute, law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any Governmental Authority or Regulatory Authority.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

“**Licensed Know-how**” means any unpatentable or unpatented developments, proprietary knowledge, ideas, specifications, prototypes, drawings, know-how, formulas, information, data, methods, processes, tools, designs, testing programs, expertise, concepts or techniques, and similar knowledge not known by Licensee prior to Licensor disclosing such knowledge to Licensee, solely to the extent that they are (a) pertinent to the Licensed Patents, (b) not subject to the exclusive rights of any third parties or research sponsor restrictions, (c) (i) in existence, and known to the Inventor or members of his laboratory(ies), as of the Effective Date or (ii) generated by or on behalf Licensor (solely or jointly with others) during the Term through the exercise of Licensor’s retained rights under Section 2.4.1, including non-clinical and clinical data (including clinical data generated in connection with the Phase I Clinical Trial for TNBC), and (d) applicable primarily within the Fields, further described in Appendix A.

“**Licensed Know-how Product**” means a product or part of a product in the Fields that is sold, transferred, or otherwise disposed of in a jurisdiction where (i) a Licensed Patent has expired; (ii) patent protection is not pursued, but the product or part of a product sold, transferred, or otherwise disposed of would be expected to infringe (with respect to Valid Claims of patent applications) any Valid Claim; or (iii) that was derived from, utilizes, uses, is used, or made through use of, embodies, contains, incorporates (in each case, in whole or in part), or uses any element of any of the Licensed Know-how.

“**Licensed Know-how Royalty Term**” means, with respect to a particular Licensed Product in a particular country, the period of time commencing on the First Commercial Sale of such Licensed Product in such country and ending on the \*\*\* of such First Commercial Sale.

“**Licensed Patents**” means the patents and patent applications listed on Appendix A, together with (a) all patents that issue therefrom, and (b) and all corresponding foreign patents and patent applications thereof, together with all divisionals, continuations (but excluding continuations-in-part), reissues, reexaminations, extensions or renewals of any of the foregoing having the same priority date as the parent and listing at least one of the Inventors as inventors.

“**Licensed Patent Challenge**” has the meaning set forth in Section 6.5(a).

“**Licensed Patent Royalty Term**” means, with respect to a particular Licensed Product in a particular country, the period of time commencing on the First Commercial Sale of such Licensed Product in such country and continuing through the date of expiration of the last to expire Valid Claim of the Licensed Patents covering the sale of such Licensed Product in such country.

“**Licensed Patent Product**” means any product or part of a product in the Fields the making, use, sale, offer to sell, or import of which infringes or would be expected to infringe (with respect to Valid Claims of patent applications) a Valid Claim, but for the license granted in this Agreement.

“**Licensed Product**” means (i) a Licensed Patent Product; or (ii) a Licensed Know-how Product.

“**Licensed Technology**” means, collectively, the Licensed Patents and the Licensed Know-How.

“**Licensee**” has the meaning set forth in the Preamble.

“**Licensor**” has the meaning set forth in the Preamble.

“**Losses**” means all losses, damages, liabilities, deficiencies, claims, actions, judgments, settlements, interest, awards, penalties, fines, costs or expenses of whatever kind, including reasonable attorneys’ fees and the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance providers.

“**Net Sales**” means the total gross amount of monies or cash equivalent or other consideration paid or payable to Licensee or any Sublicensee for sales of Licensed Products less the sum of the following amounts, without duplication: \*\*\*.

**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

For non-cash and partial-cash sales, the applicable Licensed Product shall be considered sold at the fair market value of the consideration received. For sales not at arms-length, Net Sales shall be equal to the fair market price of such Licensed Products as when transferred in comparable arms-length transactions.

In the event that Licensed Products are used by Licensee or Sublicensees for demonstration or marketing purposes rather than sold, the Parties shall agree upon an appropriate Net Sales price, if at all applicable based upon the nature and circumstance regarding the demonstration or marketing purposes, for each such use. Further, any transfer or use of a Licensed Product for clinical trials or compassionate use will not be deemed a sale for purposes of calculating Net Sales.

For the purposes of calculating Net Sales, all calculations of Net Sales shall be in accordance with GAAP and based on, or valued as if based on, bona fide arms' length transactions and not on any bundled, loss-leading or other blended or artificial selling or transfer price.

Net Sales shall not include Sublicensing Revenue.

Where Licensed Products are not sold, but are otherwise transferred or disposed of, the Net Sales amount of such Licensed Product for the purposes of computing the Earned Royalty shall be the average Net Sales price at which Licensed Products, sold in similar quantities and similar locations, are then currently being offered for sale by Licensee or its Sublicensees. Where such products are not then currently being offered for sale by Licensee or a Sublicensee, the Net Sales price of products otherwise disposed of, for the purpose of computing the Earned Patent Royalty and the Earned Know-how Royalty, shall be the average selling price at which products of similar kind and quality, sold in similar quantities and similar locations, are then currently being offered for sale by other manufacturers.

In the event that a Licensed Product is sold together with one or more products or services that are not Licensed Products for a single price (a “**Combination**”), the gross amount invoiced for such Licensed Product for purposes of calculating Net Sales shall be calculated by multiplying the gross amount invoiced for such Combination by the fraction  $A/(A+B)$ , where “A” is the gross amount invoiced for such Licensed Product sold separately and “B” is the gross amount invoiced for such other product(s) or service(s) sold separately. In the event that such Licensed Product or such other product(s) or service(s) are not sold separately, the portion of the gross amount invoiced for such Combination that is attributable to Net Sales for purposes of royalty determination shall be mutually agreed by the Parties in good faith based upon the relative value of the Licensed Product and the other product(s) or service(s) included in the Combination.

The expression “**transferred or otherwise disposed of**” means (y) not sold but delivered, directly or indirectly, by Licensee or Sublicensees to others (including deliveries for export), regardless of any return or exchange consideration; or (z) exploited or otherwise used by Licensee or Sublicensees for any purpose other than routine testing of such Licensed Products.

“**Notice**” has the meaning set forth in [Section 9.2.2](#).

“**Patenting Costs**” means any and all reasonable, documented, out-of-pocket costs and expenses, including without limitation government fees and attorneys’ fees and costs, of preparing, filing, prosecuting, issuing and maintaining any of the Licensed Patents, including continuations, extensions, re-examinations, reissues and appeals.

“**Patent Reimbursement Amount**” has the meaning set forth in [Section 6.2.1](#).

**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

“**Person**” means any individual, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, or other legal entity of any kind, foreign or domestic.

“**Phase I Clinical Trial**” means an FDA (or other foreign regulatory authority) approved dose escalating safety study with respect to a Licensed Product.

“**Phase I Clinical Trial for TNBC**” means the trial funded by the DoD for the purpose of identifying the maximally tolerated dose of a-lactalbumin and adjuvant in TNBC patients who have been in remission for 6 months and the minimally effective dose of a-lactalbumin and adjuvant in the same patients for eliciting a T-cell response.

“**Phase II Clinical Trial**” means a human clinical study of a Licensed Product, the principal purpose of which is a determination of safety and efficacy in the target patient population, as described in 21 C.F.R. 312.21(b), or a similar human clinical study prescribed by the Regulatory Authority in a country other than the United States. Phase II Clinical Trial also includes the portion of any human clinical study that meets the foregoing definition, as in the case of a study designated as a “Phase I/II” clinical trial.

“**Phase III Clinical Trial**” means a human clinical study of a Licensed Product, the design of which is acknowledged by the FDA to be sufficient for such clinical study to satisfy the requirements of 21 C.F.R. 312.21(c), or a similar human clinical study prescribed by the Regulatory Authority in a country other than the United States. Phase III Clinical Trial also includes (a) the portion of any human clinical study that meets the foregoing definition, as in the case of a study designated as a “Phase II/III” clinical trial, and (b) any other human clinical study serving as a pivotal study from which the data are actually submitted to the applicable Regulatory Authority in connection with an application for Regulatory Approval, whether or not such study is expressly designated as a “Phase III” clinical trial.

“**Product Report**” has the meaning set forth in [Section 5.3](#).

“**Quarterly Period**” means each three-month period commencing on January 1, April 1, July 1 and October 1.

“**Receiving Party**” has the meaning set forth in [Section 8.1](#).

“**Regulatory Approval**” means any approvals (including supplements, amendments, pre- and post-approvals and price approvals), licenses, registrations or authorizations, howsoever called, of any Regulatory Authority, which are necessary for the distribution, importation, exportation, manufacture, production, use, storage, transport or clinical testing and/or sale of a Licensed Product in a regulatory jurisdiction.

“**Regulatory Authority**” means the United States Food and Drug Administration (“**FDA**”) or any counterpart of the FDA outside the United States, or other national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council, ethics committee, review board or other entity with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport or clinical testing and/or sale of a Licensed Product.

“**Regulatory Filings**” means any filings, and all data contained therein, as may be required by the FDA or equivalent foreign Regulatory Authorities for the development, manufacture or commercialization of a Licensed Product hereunder.

“**Representatives**” means a party's employees, officers, directors, consultants and legal advisors.

**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

“**Reserved Interests**” has the meaning set forth in Section 2.7.

“**Responsible Officer**” with respect to any Person, means the chief executive officer, president or chief financial officer of such Person.

“**Review Period**” has the meaning set forth in Section 2.4.2.

The terms “**sale**”, “**sold**” and “**sell**” as used in this Agreement include without limitation sales, leases, licenses, rentals and other modes of distribution or transfer of a product or its beneficial use. Licensed Products will be considered sold when delivered or invoiced, whichever occurs first.

“**Sublicense**” shall mean an agreement in which Licensee (a) sublicenses any of the rights licensed to Licensee hereunder, (b) agrees not to assert such rights or to sue, prevent or seek a legal remedy for the practice of same, or (c) is under an obligation to grant, assign or transfer any such rights or non-assertion, or to forebear from granting or transferring such rights to any other entity. Agreements expressly considered Sublicenses includes without limitation licenses, option agreements, or similar agreements, to the extent that the rights granted therein relate to the rights licensed to Licensee hereunder.

“**Sublicense Fees**” has the meaning set forth in Section 3.4.

“**Sublicensee**” shall mean any non-Affiliate third party to whom Licensee has granted a Sublicense.

“**Sublicensing Revenue**” shall mean any and all consideration received by Licensee from sublicensing any of the rights granted to it under Section 2.1 of this Agreement, including without limitation cash and cash equivalents, license issue fees and other licensing fees, option fees, milestone payments, or other payments of any kind, but excluding royalties on sales of Licensed Products and minimum annual royalties.

“**Taxes**” means any and all present or future income, stamp or other taxes, levies, imposts, duties, deductions, charges, fees or withholdings imposed, levied, withheld or assessed by any Governmental Authority, together with any interest, additions to tax or penalties imposed thereon and with respect thereto.

“**Term**” has the meaning set forth in Section 7.1.

“**Territory**” means worldwide.

“**Valid Claim**” means any pending or issued claim of any Licensed Patent that has not been admitted by Licensor or otherwise caused to be invalid or unenforceable through reissue, disclaimer or otherwise, or held invalid or unenforceable by a Governmental Authority of competent jurisdiction from whose judgment no appeal is allowed or timely taken.

1.2 Interpretation.

(a) For purposes of this Agreement: (i) the words "include," "includes" and "including" shall be deemed to be followed by the words "without limitation"; (ii) the word "or" is not exclusive; and (iii) the words "herein," "hereof," "hereby," "hereto" and "hereunder" refer to this Agreement as a whole.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

(b) 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) The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Unless the context otherwise requires, references herein: (i) to Sections, Appendices and Exhibits refer to the Sections, Appendices and Exhibits attached to, this Agreement; (ii) to an agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof; and (iii) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. This Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted. Any Appendices and Exhibits referred to herein shall be construed with, and as an integral part of, this Agreement to the same extent as if they were set forth verbatim herein.

(d) All accounting terms not specifically or completely defined herein shall be construed in conformity with, and all financial data required to be submitted pursuant to this Agreement shall be prepared in conformity with, GAAP as in effect from time to time.

Article 2

GRANT; SUBLICENSING

2.1 License Grant.

(a) Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee (i) the exclusive worldwide (as to the countries for which patent protection is sought) license, with the right to grant and authorize Sublicenses as set forth below, under the Licensed Patents to make, have made, use, offer to sell, sell and import Licensed Products in the Fields in the Territory, and (ii) a non-exclusive worldwide license, with the right to grant and authorize Sublicenses as set forth below, to use or practice the Licensed Know-How to make, have made, use, offer to sell, sell and import Licensed Products in the Fields in the Territory.

(b) Licensor shall, within \*\*\* after the Effective Date, disclose the Licensed Know-how to Licensee in accordance with Article 12. Licensee acknowledges and agrees that the Licensed Know-how is considered Confidential Information and has independent value and will provide Licensee with a competitive advantage and/or commercial value. Licensed Know-how includes \*\*\* and other information as described in Appendix A. In addition, Licensor shall (i) disclose to Licensee all Licensed Know-how generated during the Term, including non-clinical and clinical data, within \*\*\* after such Licensed Know-how is generated, in an electronic format reasonably acceptable to Licensee, and (ii) obtain such consents from third parties as may be necessary to make such disclosures to Licensee, including informed consents from subjects participating in clinical trials, as applicable. For clarity, clinical data delivered in accordance with the preceding sentence shall include raw data and case report forms.

2.2 Sublicensing.

(a) Licensee may sublicense the rights granted to it under Section 2.1, \*\*\*, so long as, \*\*\*, (w) \*\*\*, (x) this Agreement has not been terminated, (y) Licensee is not in breach of its obligations hereunder (or there is not otherwise a continuing Default), and (z) the following criteria are satisfied:

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

- (i) the Sublicense is in writing;
  - (ii) \*\*\*;
  - (iii) \*\*\*; and
  - (iv) \*\*\*.
- (b) \*\*\*.
  - (c) \*\*\*.
  - (d) \*\*\*.

(e) Licensee will provide Licensor with (i) a fully signed, copy of each Sublicense granted by Licensee under this Agreement and any amendments thereto, including all exhibits, attachments and related documents, within thirty (30) days of executing the same, (ii) a copy of all reports provided to Licensee by Sublicensees during the term of the Sublicense on a quarterly basis; and (iii) notification of the termination of any Sublicense, in each case, which information will be Licensee’s Confidential Information. Notwithstanding any Sublicense, Licensee shall remain primarily liable to Licensor for all of Licensee's duties and obligations contained in this Agreement, including, without limitation, the payment of all Earned Royalties due hereunder. Any act or omission of a Sublicensee that would be a breach of this Agreement if committed or omitted by Licensee will be a breach by Licensee.

2.3 Government Rights. Notwithstanding anything herein to the contrary, any and all provisions contained herein, (including without limitation, the licenses and other rights granted hereunder and all representations and warranties of Licensor) are limited by and subject to the rights and requirements of the United States Government that may attach as a result of U.S. Government sponsorship, in any way, of research at Licensor in which one or more invention covered by the Licensed Patents was conceived or first actually reduced to practice, as set forth in 35 U.S.C. §§200-206, 37 C.F.R. Part 401 and in the relevant Government research contracts with Licensor, and as such rights and requirements may be amended or modified by Law. To the extent applicable, such rights and requirements include without limitation (i) the grant of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the U.S. Government any of the Licensed Patents throughout the world (as set forth in 35 U.S.C. §202(c)(4)), and (ii) the requirement that Licensed Products used or sold in the United States will be manufactured substantially in the United States (as set forth in 35 U.S.C. §204) (provided that if Licensee seeks a waiver to manufacture Licensed Products outside of the United States, Licensor will reasonably cooperate at Licensee’s cost and expense, where applicable).

2.4 Retained Rights; Requirements.

2.4.1 Research Use Right. Any and all licenses granted hereunder are subject to the right of Licensor, on behalf of itself and its investigators, to practice and use the Licensed Patents and the subject matter described and/or claimed therein, and to permit others at academic, government, and not-for-profit institutions to practice and use the Licensed Patents and the subject matter described and/or claimed therein, for its and their own research (including without limitation, pre-clinical, non-clinical and clinical research), testing, educational, internal or patient-care purposes. For avoidance of any doubt, any research previously performed, currently being performed, or performed in the future by Licensor, at Licensor’s facilities or using Licensor’s resources, or that Licensor or Inventor is in any way related to (whether as Principal Investigator, sponsor or otherwise) is subject to the retained rights in this Section 2.4.1 (the “**Permitted Research**”). Permitted Research includes, without limitation, the Phase I Clinical Trial for TNBC and any research activities of Licensor or Inventor (while an employee of Licensor) that are funded in whole or in part by any Governmental Authorities or any philanthropic or similar sources. For clarity, Licensor agrees and acknowledges that this Section 2.4.1 does not give Licensor the right to practice or use the Licensed Technology in connection with the commercial sale of any product or service.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

2.4.2 Right to Publish. Licensee recognizes and accepts the importance of communicating medical study and scientific data and the necessity of conveying such information in a timely manner, and, therefore, encourages their publication in reputable scientific journals and at seminars or conferences, even if such publication includes Licensed Know-how. Licensee further recognizes and accepts that under Licensor’s mission as an academic medical center, Licensor and its investigators must have a meaningful right to publish without Licensee’s approval or editorial control. Licensor shall submit to Licensee for its review a copy of any proposed manuscript \*\*\* prior to the estimated date of submission for publication. Within \*\*\* of receiving such manuscript (the “**Review Period**”), if Licensee reasonably determines that the proposed publication contains patentable subject matter which requires protection for Licensee, Licensee may require the delay of publication for a period of time not to exceed \*\*\* for the purpose of filing patent applications. Further, Licensor and its investigators agree to remove from the proposed publication anything that Licensee identifies within the Review Period as Licensee’s Confidential Information. If no written response is received from Licensee within the Review Period, it may be conclusively presumed that publication may proceed without delay. For avoidance of any doubt, Licensor and Inventor (while an employee of Licensor) retain the right to publish any medical study or scientific data arising from the Permitted Research, subject to compliance with this Section 2.4.2.

2.5 Regulatory Affairs.

(a) Licensor hereby grants Licensee, and its Affiliates and Sublicensees, a “right of reference,” as that term is defined in 21 C.F.R. § 314.3(b), or a comparable right existing under the Laws of any other jurisdiction, to any Regulatory Filings owned or otherwise controlled by Licensor or its Affiliates to the extent relating to the research, development, manufacture or commercialization of a Licensed Product in the Fields in the Territory, and, upon request, shall promptly provide a signed statement to such effect in accordance with 21 C.F.R. §314.50(g)(3) or the Laws of any other jurisdiction.

(b) Licensee shall have the right to audit any clinical data included in the Licensed Know-how (“**Licensed Clinical Data**”) for accuracy and completeness, upon at least \*\*\* prior written notice, at Licensee’s sole expense, including but not limited to any incidental costs incurred by Licensor as a result of any such audit. If a Regulatory Authority requests that Licensee provide additional information regarding any Licensed Clinical Data, then the parties shall discuss the scope of such request and, if the requested information is owned or otherwise controlled by Licensor, Licensor shall provide such information to Licensee in a reasonable amount of time and cooperate with Licensee in responding to such request.

(c) Licensor shall provide Licensee with prompt written notice of an impending inspection by a Regulatory Authority relating to the Licensed Clinical Data and the results of such inspection, including any FDA Form 483 notices (or similar notices of other Regulatory Authorities). Further, if a Regulatory Authority makes any finding that impacts or could reasonably be expected to impact the Licensed Clinical Data, then Licensor shall provide Licensee with prompt written notice thereof and solicit (and reasonably consider) Licensee’s feedback regarding any plan for remedial action.

(d) Licensor does not represent or warrant that any Licensed Clinical Data was created in accordance with or pursuant to any requirements under the C.F.R, or any comparable Laws of any jurisdiction. Furthermore, Licensor does not represent or warrant that any Licensed Clinical Data was created for submission to any Governmental Authority.



**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

2.6 No Grant of Other Technology or Patent Rights. Except as otherwise expressly provided in this Agreement, under no circumstances shall Licensee, as a result of this Agreement obtain any ownership interest or license in or other right to any technology, know-how, patents, patent applications, products, or materials of Licensor, including items owned, controlled or developed by Licensor, at any time pursuant to this Agreement. This Agreement does not create, and shall under no circumstances be construed or interpreted as creating, an obligation on the part of Licensor to grant any license to Licensee other than as expressly set forth herein. Any further contract or license agreement between the parties shall be in writing.

2.7 Reserved Rights. All rights and interests of Licensor not expressly granted to Licensee are reserved by Licensor (the “**Reserved Interests**”) for itself, its Affiliates and partners (other than Licensee) and other licensees and Sublicensees, including the rights to use and grant licenses under the Licensed Patents or any other technology owned or controlled by Licensor to make, have made, use, offer to sell, sell, have sold and import products (other than Licensed Products within the Fields for so long as Licensee has an exclusive license to Licensed Products within the Fields under this Agreement). It shall not be a breach of this Agreement for Licensor, acting directly or indirectly, to exploit its Reserved Interests in any manner anywhere in the Territory, whether or not such activity is competitive with the activities of Licensee, including the research, development and commercialization or licensing of others to research, develop and commercialize products (other than Licensed Products within the Fields for so long as Licensee has an exclusive license under the Licensed Patents to develop and commercialize products within the Fields under this Agreement), including products that potentially compete in the same product market as a Licensed Product); provided that the foregoing shall not be construed to be a grant of any license, implied or otherwise, by Licensee to Licensor or to permit Licensor to breach the confidentiality provisions of this Agreement.

Article 3  
FINANCIAL CONSIDERATION

3.1 Issue Fee. In consideration of its license to the Licensed Technology hereunder, Licensee shall pay to Licensor a non-refundable, non-creditable license fee in an amount equal to \*\*\* dollars (\$\*\*\*) (the “**Issue Fee**”), payable to Licensor \*\*\*.

3.2 Earned Royalties.

(a) In consideration of its license to the Licensed Patents hereunder, Licensee shall pay to Licensor a quarterly royalty equal to \*\*\* of the Net Sales (the “**Earned Patent Royalty**”) of a particular Licensed Product sold, transferred or otherwise disposed of in a particular country where a Valid Claim exists covering the sale of such Licensed Product in such Country during the Licensed Patent Royalty Term for such Licensed Product in such country.

(b) In consideration of its license to the Licensed Know-how hereunder, Licensee shall pay to Licensor a quarterly royalty equal to \*\*\* of the Net Sales (the “**Earned Know-how Royalty**”) of a particular Licensed Product sold, transferred or otherwise disposed of in a particular country where no Valid Claim exists covering the sale of such Licensed Product in such country during the Licensed Know-how Royalty Term for such Licensed Product in such country. For avoidance of doubt, during the Licensed Know-how Royalty Term for a particular Licensed Product in a particular country, Earned Know-how Royalties shall be payable in respect of sales of such Licensed Product in such country if there are no Valid Claims covering the sale of such Licensed Product in such country.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

(c) The Earned Patent Royalty and the Earned Know-how Royalty shall not be cumulative, such that only one Earned Royalty (*i.e.*, the Earned Patent Royalty or the Earned Know-how Royalty, as applicable) will be payable with respect to any Licensed Product sold during the Term.

3.3 **Annual Maintenance Fee.** In consideration of its license to the Licensed Technology hereunder, for the first calendar year beginning after the Effective Date and each subsequent calendar year thereafter, but before the year of the First Commercial Sale, Licensee shall pay to Licensor an “**Annual Maintenance Fee**” in the amount of \$\*\*\*. The first Annual Maintenance Fee shall be due and payable on or before January 15, 2021, and thereafter Licensee shall pay the Annual Maintenance Fee to Licensor within \*\*\* of the end of each calendar year for which an Annual Maintenance Fee is required. The Annual Maintenance Fee shall be fully creditable against any Milestone Payment received for such calendar year.

3.4 **Sublicense Fees.** In consideration of its license to the Licensed Technology hereunder, Licensee shall pay to Licensor sublicense fees (“**Sublicense Fees**”) for any Sublicense executed by the milestone and in an amount equal to a percent of Sublicensing Revenue, in each case identified in the table below. Consideration received by Licensee as Sublicensing Revenue in the form of equity or other securities shall be paid to Licensor in kind, and consideration received as Sublicensing Revenue in the form of goods shall be paid to Licensor in cash based upon the fair market value of such goods received.

<b>Milestone</b>	<b>Sublicense Rate</b>
***	***
***	***
***	***
***	***

For purposes of this Section 3.4, \*\*\*.

3.5 **Minimum Annual Royalty.**

(a) In consideration of its license to the Licensed Technology hereunder, Licensee shall pay to Licensor a minimum annual royalty (each, a “**MAR**”) with respect to all Licensed Products, as set forth in the table below:

<b>Year</b>	<b>MAR</b>
***	***
***	***
***	***
***	***

(b) Each year’s MAR payment shall be due and payable within \*\*\* following the end of the calendar year to which it applies (e.g., the 2019 MAR is due and payable on or before February 14, 2020). If the total amount of Earned Royalties paid during any calendar year exceeds the MAR for such calendar year, then Licensee shall have no MAR payment obligation for such calendar year. In no event will the MAR be pro-rated for any partial calendar year. The MAR shall be fully creditable against any Milestone Payment received for such calendar year.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

3.6 Product Development Milestone Payments. In consideration of its license to the Licensed Technology hereunder, Licensee shall pay to Licensor the following payments (each, a “**Milestone Payment**”) within \*\*\* of the completion or occurrence of each Milestone Activity with respect to a Licensed Product:

<b>Amount</b>	<b>Milestone Activity</b>
***	***
***	***
***	***

For purposes of this Agreement, \*\*\*. For the avoidance of doubt, each Milestone Payment shall be paid only for the first Licensed Product to complete the Milestone Activity.

3.7 Payment Terms.

(a) Licensee shall pay all Earned Royalties and Sublicense Fees for each Quarterly Period within \*\*\* of the end of such Quarterly Period. Licensee shall make all payments under this Agreement in US dollars. If any payments required hereunder are not received by Licensor on the date the same has become due and payable, Licensee shall pay to Licensor interest on the overdue undisputed payment from the date such payment was due to the date of actual payment at a rate of \*\*\*, or if lower, the maximum amount permitted under applicable Law.

(b) Earned Royalties, MAR payments, Milestone Payments, Sublicense Fees and all other sums payable by Licensee under this Agreement shall be made free and clear of and without deduction or withholding for any Taxes except as required by applicable Law. If Licensee is required by applicable Law to deduct or withhold any Taxes from such payments, then: (i) the amount payable by Licensee shall be increased so that after all such required deductions or withholdings are made (including deductions or withholdings applicable to additional amounts payable under this Section), Licensor receives an amount equal to the amount it would have received had no such deduction or withholding been made; and (ii) Licensee shall make such deductions or withholdings and timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with applicable Law. As soon as practicable after any payment of Taxes by Licensee to a Governmental Authority pursuant to this Section, Licensee shall deliver to Licensor the original or certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the relevant return reporting such payment or other evidence of such payment reasonably satisfactory to Licensor.

(c) For the purpose of converting the local currency in which any royalties or other payments arise into US dollars, the rate of exchange to be applied shall be the rate of exchange in effect on the last business day of the calendar quarter to which the payment relates as reported in the Wall Street Journal.

(d) If at any time any payment made by Licensee under this Agreement is rescinded or must otherwise be restored or returned upon the insolvency, bankruptcy or reorganization of Licensee or otherwise, Licensee’s obligation to make such payment shall be reinstated as though such payment had not been made.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

3.8 Royalty Stacking. If Licensee determines that it is necessary that Licensee obtain a license from any third party (“**Third Party License**”) in order to avoid infringing that third party’s intellectual property rights in the manufacture, use, sale and/or importation of the Licensed Products, the royalty rate paid to Licensor shall be reduced by \*\*\* of the royalty rate paid for such additional patent or intellectual property rights (i.e. \*\*\*); provided, however, that in no event shall the royalty rate paid to Licensor be less than \*\*\* for Licensed Patent Products or \*\*\* for Licensed Know-how Products. Upon request, Licensee will promptly provide to Licensor reasonable documentation supporting the determination contemplated by this Section, provided that Licensee will not be required to disclose information subject to the attorney-client privilege.

This Section applies only to any prospective earned royalty payable to third parties for rights required to permit Licensee to make, use, offer to sell, sell and import the Licensed Product as provided in this Agreement, and no deduction of any Earned Royalty is allowed for payments to any third party of lump sum license fees, milestone payments, minimum annual royalties in excess of accrued royalties, any amounts paid for past infringement of any third-party's rights or any amount not paid for rights required to permit Licensee to make, use, offer to sell, sell and import the Licensed Product as provided in this Agreement.

Article 4

COMMERCIALIZATION AND DEVELOPMENT COVENANTS

4.1 Commercialization and Development Milestones.

(a) Licensee agrees to use commercially reasonable efforts to \*\*\*. In furtherance of, and without limiting, the foregoing, Licensee agrees to cause the occurrence of each of the following milestones (each, a “**Milestone**”) by the corresponding milestone date (each, a “**Milestone Date**”):

<b>Milestone</b>	<b>Milestone Date</b>
***	***
***	***
***	***
***	***

When Licensee completes a Milestone by the applicable Milestone Date, it will provide Licensor with written notice of the achievement of the Milestone within \*\*\* of such completion, together with documentation evidencing such achievement. Any efforts of Licensee or its Affiliates and Sublicensees, or of Licensor or its Affiliates, will be deemed to be the efforts of Licensee for purposes of satisfying the obligations of this Section 4.1.

For purposes of this Section 4.1, \*\*\*.

(b) \*\*\*.

(c) \*\*\*.

4.2 Updates.

(a) Not later than July 31 of each year prior to the First Commercial Sale, Licensee shall deliver a Development Report to Licensor.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

(b) Not later than July 31 of each year prior to the First Commercial Sale, Licensee will provide to Licensor an update on the activities described in the Development Plan, in form and substance reasonably acceptable to Licensor in its reasonable discretion, describing in reasonable detail the material activities to be undertaken during the next \*\*\* and the estimated timing of such activities, including the estimated dates of the initiation and completion of such activities and a summary of Licensee’s material product development activities since the prior Annual Update (the “**Annual Update**”). Licensee’s obligation to provide Licensor with Annual Updates will continue for a Licensed Product until the First Commercial Sale of such Licensed Product. All such Development Reports and Annual Updates under this Section 4.2 shall be deemed Licensee’s Confidential Information.

(c) During the Term, Licensor shall promptly deliver to Licensee copies of such periodic reports that Licensor provides to the Department of Defense or other source of grant funding in connection with the development of Licensed Products (including progress reports and financial reports) and shall promptly provide Licensee with copies of all material correspondence with any such source of grant funding relating to the development of Licensed Products.

4.3 Regulatory Approval. Licensee and its Affiliates and Sublicensees will be solely responsible, at their sole cost and expense, for making all Regulatory Filings and securing all Regulatory Approvals, except to the extent performed by Licensor in accordance with Section 2.4.1. Licensee will provide notice to Licensor of the submission of all Regulatory Filings (including amendments to prior filings and correspondence related to any such filings) to Licensor within \*\*\* following the submission thereof. Licensee will provide copies of all Regulatory Approvals to Licensor within \*\*\* following the receipt thereof. Licensor will provide reasonable cooperation through providing Licensee, upon Licensee’s written request and in a timely fashion, with all documentation and information reasonably necessary to secure such Regulatory Approval, to the extent such documentation and information is in Licensor’s possession and not subject to any confidentiality or non-disclosure obligations.

Article 5

ADDITIONAL COVENANTS; CLOSING CONDITIONS

5.1 Books and Records. Licensee will maintain documentation detailing Licensee’s efforts to develop Licensed Products for commercial sale in the Fields in the Territory, and thereafter will maintain accurate records detailing all commercial sales of Licensed Products. Such documentation may include invoices for studies advancing development of Licensed Products, laboratory notebooks, internal job cost records, filings made to the Internal Revenue Service to obtain tax credit, if available, for research and development of Licensed Products, records relating to obtaining Regulatory Approval, and sales records of Licensee or Sublicensees. Such books and records will be preserved for a period not less than \*\*\* after they are created during and after the Term.

5.2 Financial Audit. Upon reasonable notice and during regular business hours, Licensee will allow Licensor or its designee, at Licensor’s sole expense, to review (and audit) all books and records, including financial records, and inspect Licensee’s research and development facilities, in each case solely to verify the accuracy of Licensee’s Development Reports and Product Reports and Licensee’s compliance with its obligations, covenants and agreements under this Agreement; provided that Licensor will conduct such audit no more than \*\*\*, upon reasonable notice, in a manner that does not interrupt Licensee’s operations, and not later than \*\*\* following the rendering of any such records pursuant to Section 5.1. Licensee shall also use commercially reasonable efforts to obtain a comparable right for Licensee to audit any Sublicensees, and, in the event Licensee obtains such right, shall perform a comparable audit of a Sublicensee and provide Licensor a summary of such audit upon Licensor’s written request. Should any of the foregoing examinations reveal an underpayment, then Licensee shall immediately pay to Licensor the underpaid amount, plus interest in the amount provided for in Section 3.6 (Payment Terms). Further, if such underpayment exceeds \*\*\* of the amount paid by Licensee to Licensor in the previous calendar year under this Agreement, then Licensee shall bear the reasonable out-of-pocket cost of such audit, including accountants’ and attorneys’ fees and expenses, and shall immediately reimburse Licensor for all such costs incurred by Licensor.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

5.3 Product Reports. Commencing in the Quarterly Period in which the First Commercial Sale occurs, within \*\*\* of the end of each Quarterly Period, Licensee shall deliver to Licensor a complete and accurate product report (each, a “**Product Report**”), giving such particulars of the business conducted by Licensee and Sublicensees during the preceding Quarterly Period under this Agreement as shall be pertinent to a royalty accounting hereunder. Without limiting the generality of the foregoing, the Product Reports shall be in substantially the form of Exhibit B attached hereto and include at least the following on a Licensed Product-by-Licensed Product basis:

\*\*\*

Upon termination of this Agreement, Product Reports accompanied by any applicable Earned Royalties and Sublicense Fees shall continue to be due until a final Product Report is submitted, which shall be due within \*\*\* following the termination of this Agreement. All Product Reports shall be deemed Licensee’s Confidential Information.

5.4 Compliance Certificate. Together with each Product Report, Licensee shall deliver a duly executed compliance certificate from a Responsible Officer stating that (a) all such reports are true, accurate and correct in all material respects, (b) Licensee during such period has observed and performed all of the covenants and other agreements, and satisfied every condition contained in this Agreement to be observed, performed or satisfied by it, and that there has not occurred any Default except as specified in such certificate.

5.5 Affirmative and Negative Covenants. During the Term, Licensee shall:

(a) not take any action, or omit to take any action, if in the reasonable judgment of Licensor such act or omission has had, or could reasonably be expected to have, an adverse impact upon or to the brand, name, goodwill or image of Licensor;

(b) not use, practice, commercialize or otherwise exploit the Licensed Technology outside the Fields, excluding Licensed Know-how that becomes generally known to the public or otherwise becomes publicly available, other than through a breach of this Agreement by Licensee;

(c) comply with all Laws applicable to the conduct of Licensee’s business and activities related to developing, manufacturing, marketing, offering for sale, selling, importing and exporting Licensed Products.

5.6 Notices. Licensee shall promptly give notice to Licensor of:

(a) the occurrence of the First Commercial Sale; and

(b) the occurrence of any Default.

5.7 Development Plan. Licensee shall provide to Licensor a copy of a Development Plan after Completion (as defined in Section 3.4) of a Phase I Clinical Trial and prior to the dosing of the first patient in a Phase II Clinical Trial, which shall be attached hereto as Exhibit A, which Development Plan shall be deemed to be Licensee’s Confidential Information.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

Article 6

PATENT PROSECUTION; INFRINGEMENT

6.1 Patent Prosecution. Licensor shall have exclusive responsibility for the preparation, filing, prosecution, issuance and maintenance of the Licensed Patents, using counsel reasonably acceptable to Licensee. Licensor shall keep Licensee informed of patent prosecution, shall keep Licensee reasonably informed and copied on all correspondence, shall provide Licensee with copies of all prosecution documentation (including office actions and draft patent applications) reasonably in advance of applicable deadlines such that Licensee has a reasonable opportunity to review and comment, will consider Licensee’s comments and suggestions prior to taking material actions for the same, and will take all prosecution actions reasonably recommended by Licensee that would expand the scope of rights sought. The parties shall reasonably cooperate with each other to insure that each Licensed Patent reflects and will reflect, to the extent practicable and to the best of Licensee’s knowledge, all items of commercial interest to Licensee. Licensor shall notify Licensee at least \*\*\* prior to any deadline if it intends to abandon, or otherwise elect to forego its rights in, any Licensed Patents and Licensee shall have the right (but not the obligation) to assume control of the preparation, filing, prosecution, issuance and maintenance of such Licensed Patents in the name of Licensor and at Licensee’s expense.

6.2 Patent Reimbursements.

6.2.1 Licensee shall reimburse Licensor for all Patenting Costs incurred by Licensor as of the Effective Date (the “**Patent Reimbursement Amount**”) in an amount equal to \$\*\*\*. Payment by Licensee of the Patent Reimbursement Amount shall be due \*\*\*.

6.2.2 Licensee will be responsible for the payment of all Patenting Costs incurred or to be incurred by Licensor after the Effective Date.

6.2.3 With respect to any action necessary to protect a particular Licensed Patent in a particular country in the Territory, if Licensee instructs Licensor in writing not to take such action, the rights protected by such Licensed Patent shall be excluded from the license granted herein and Licensee shall be relieved from its obligation to pay for future Patenting Costs relating to such Licensed Patent in such country. Thereafter, Licensor shall have the right to (i) abandon some or all of such rights at Licensor’s sole discretion, or (ii) incur those costs at its own expense; in either case, Licensor shall be free to license such rights to third parties without any further obligation to Licensee.

6.3 [Reserved]

6.4 Enforcement of Licensed Patents.

6.4.1 Notice. If either party becomes aware of any infringement, anywhere in the Territory, of any issued patent within the Licensed Patents, such party will notify the other party of such infringement in writing as soon as reasonably practical thereafter (the “**Infringement Notice**”).

6.4.2 Infringement of Licensed Patents by Third Parties

(a) In the case of any infringement within the Fields of any Licensed Patent by any third party during the Term, Licensee will have the first right, but not the obligation, at Licensee’s expense, to cause such third party to cease infringement and to otherwise enforce such Licensed Patent, or to defend the Licensed Patent, or to defend the Licensed Patent in any declaratory judgment action brought by third parties that alleges the invalidity, unenforceability or non-infringement of the rights associated with the Licensed Patent in the Fields; provided, however, that Licensee will (i) use counsel reasonably acceptable to Licensor, (ii) keep Licensor reasonably informed regarding the progress of any litigation and settlement discussions with any alleged infringer, and (iii) copy Licensor on, or provide Licensor with copies of, all external documents and correspondence (i.e., documents and correspondence sent by Licensee to a third party or received by Licensee from a third party). Licensee will have control of the conduct of any such action that it brings, provided that Licensor will have the right to provide ongoing comments on documents prior to submission and advice regarding its position and interests in such action, which advice and comments will be considered in good faith by Licensee and incorporated or adopted by Licensee to the extent they are reasonable or support the validity, enforceability or scope of claims of a Licensed Patent, and (y) Licensee will not enter into any settlement, consent judgment or other voluntary disposition of any such action without the prior written consent of Licensor, which consent will not be unreasonably withheld, delayed or conditioned. For the purposes of this Section 6.4.2 (and without limiting generality of the foregoing) it will be reasonable to Licensor to withhold consent to a settlement if the settlement would admit the invalidity or unenforceability of or limit in any way any patent owned by Licensor. Licensor will, at the request and expense of Licensee, provide reasonable cooperation and assistance in any action described in this Section 6.4.2. Except for providing such reasonable assistance, Licensor will have no obligation regarding the legal actions described herein; provided, however, that Licensor will join such action at Licensee’s request and expense if such joinder is, in the opinion of Licensee’s counsel, required to enable Licensee to initiate or continue such action. Licensor, however, will have the right to participate in any such action through its own counsel and, except as provided in this Section 6.4.2(a), at its own expense.

(b) If Licensee does not, within a reasonable period after becoming aware of such infringement but no less than \*\*\* from the date of the Infringement Notice, (i) initiate legal proceedings against such threatened or actual infringement, or defend legal proceedings brought by a third party, as provided in Section 6.4.2(a), or (ii) cause such infringement to terminate, Licensor may thereafter take such action as it deems necessary to enforce its rights in the Licensed Patent, including the right, but not the obligation, to bring, at its own expense, an infringement action or file any other appropriate action or claim related to such infringement against any third party; provided, however, that Licensor shall have no obligation to bring any suit, action or other proceeding against any alleged infringer of any Licensed Patent. Licensee shall and hereby does irrevocably and unconditionally waive any objection to Licensor's joinder of Licensee to any proceeding described in Section 6.4.2(a) on any grounds whatsoever, including on the grounds of personal jurisdiction, venue or *forum non conveniens*. If Licensor brings or defends any such proceeding, Licensee shall reasonably cooperate in all respects with Licensor in the conduct thereof, and assist in all reasonable ways, including having its employees testify when requested and make available for discovery or trial exhibit relevant records, papers, information, samples, specimens, and the like at Licensee's own cost.

6.4.3 Infringement of Third Party Rights. In the event that any action, suit or proceedings brought against, or written notice of threat thereof is provided to Licensee alleging infringement of any patent or unauthorized use or misappropriation of technology arising out of or in connection with Licensee’s exercise to Licensed Patents, Licensee shall have the right to defend at its own expense such action, suit or proceeding. Licensee shall hold harmless and indemnify Licensor from and against any order to pay costs arising without fault of Licensor that may be made against Licensee or Licensor in such proceedings. Licensor agrees to cooperate with Licensee at Licensee’s expense (excluding salaries, rent, utilities and other expenses typically treated as overhead) in connection with Licensee’s response to or defense of such action, suit or proceeding, or notice of threat thereof.



**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

6.4.4 Recovery. If either party shall undertake the enforcement and/or defense of the Licensed Patents by litigation pursuant to Sections 6.4.2 and Section 6.4.3, any recovery or damages (whether by way of settlement or otherwise) received as a result of any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of either party, and then the remainder (related to the Licensed Patents) shall be divided between the Parties as follows: \*\*\*.

6.4.5 March-in Rights. If any suit, action or other proceeding alleging invalidity or non-infringement of any Licensed Patent is brought against Licensee, Licensor, at its option, shall have the right, within \*\*\* after commencement of such suit, action or other proceeding, to intervene and take over the sole defense of the suit, action or other proceeding at its own expense.

6.5 Licensed Patent Challenges.

(a) In the event that Licensee directly or indirectly disputes, challenges, or assists in the challenge of the validity, scope, construction, enforceability or Licensor’s ownership of any issued patent comprising the Licensed Patents or any claims thereof, or opposes or assists in the opposition of the grant of any Letters Patent comprising the Licensed Patents, either in a court of law, before the U.S. Patent and Trademark Office, or other agency or tribunal (“**Licensed Patent Challenge**”), then (i) Licensor has the right to immediately terminate this Agreement upon written notice to Licensee and with no opportunity for Licensee to cure, and (ii) Licensee shall pay all of Licensor’s costs, fees and expenses associated with its defense of such challenge or opposition.

(b) Licensee shall include provisions in all Sublicenses permitted under Section 2.2 providing that if the Sublicensee brings or participates in a Licensed Patent Challenge, the Sublicense will immediately terminate effective as of the first date of the Sublicensee’s first filing or participation in the Licensed Patent Challenge. The failure to include such automatic termination provision in a Sublicense hereunder shall constitute a material breach of this Agreement. If a Sublicensee undertakes a Licensed Patent Challenge, Licensee, shall immediately terminate the applicable Sublicense upon becoming aware of such Licensed Patent Challenge. Any failure to immediately terminate the Sublicense as required by this Section 6.5(b) shall constitute a material breach of this Agreement.

(c) If Licensee directly or indirectly institutes or participates in a Licensed Patent Challenge and Licensor elects not to terminate this Agreement in accordance with Section 6.5(a), then \*\*\*.

6.6 Patent Extensions. Licensee and Licensor shall use reasonable efforts in its good faith determination to extend the Licensed Patents, which may include extensions provided under U.S. law at 35 U.S.C. §154(b), 155A, and 156, provided that Licensee shall have final decision-making authority with respect to any patent term extension with respect to Licensed Products. Licensee hereby agrees to provide Licensor with all necessary assistance in securing such extensions, including without limitation, providing all information regarding applications for Regulatory Approval, approvals granted, and the timing of same. To the extent applicable, Licensee acknowledges that extensions under 35 U.S.C. §156 must be applied for within \*\*\* of the date that a Licensed Product receives permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use and that Licensee’s failure to promptly provide the necessary information or assistance to Licensor during such \*\*\* period (with respect to a Licensed Patent for which Licensee has elected to pursue a patent term extension) will cause serious injury to Licensor, for which Licensee will be liable.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

Article 7

TERM AND TERMINATION

7.1 Contract Term. This Agreement shall commence on the Effective Date and, unless terminated earlier in accordance with this Article 7 or any other applicable provisions herein (including, without limitation, Section 6.5, Section 7.2, Section 7.3, Section 7.4 or Section 7.5) shall continue until the later to occur of (i) the five (5) year anniversary of the expiration of the last to expire Valid Claim of the Licensed Patents or (ii) the ten (10) year anniversary of the First Commercial Sale in each jurisdiction. The period set forth in this Section 7.1, or such shorter periods as may result from the earlier termination of this Agreement in accordance with this Article 7 or any other provision of this Agreement, shall collectively be referred to as the “Term”.

7.2 Licensor Termination due to Licensee Insolvency.

(a) Licensor shall have the right to immediately terminate this Agreement upon written notice if Licensee:

(i) becomes subject, voluntarily or involuntarily, to any proceeding under any Debtor Relief Law, which is not fully stayed within \*\*\* or is not dismissed or vacated within \*\*\* after filing;

(ii) is dissolved or liquidated;

(iii) makes a general assignment for the benefit of creditors; or

(iv) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

7.3 Licensor Termination due to Breach of Contract Claim

(a) Licensor shall have the right to immediately terminate this Agreement upon written notice if Licensee claims that Licensor breached this Agreement through the exercise by Licensor or an academic, government, or not-for-profit institution of any of the retained rights provided in Section 2.4 of this Agreement to:

(i) perform research regarding the Licensed Technology;

(ii) publish any results of the research described in Section 7.3(a)(i), provided such publication is made in compliance with Section 2.4.2; or

(iii) disclose any results of the research described in Section 7.3(a)(i) to any Governmental Authorities, provide such disclosure is made in compliance with Section 2.4.2.

7.4 Licensor Termination for Cause.

(a) In addition to any rights of Licensor to terminate this Agreement as provided elsewhere in this Agreement, Licensor shall have the right, in its sole discretion, to terminate this Agreement upon written notice to Licensee for any of the following events:

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

(i) if Licensee fails to pay any undisputed amount under this Agreement when due and such failure remains unremedied for a period of \*\*\* after written notice to Licensee from Licensor;

(ii) if any representation, warranty, certification or other statement of fact made by or on behalf of Licensee herein, or in any certificate, document, report, financial statement or other document furnished by or on behalf of Licensee under or in connection with this Agreement or any other agreement between Licensee and Licensor, proves to have been false or misleading in any material respect on or as of the date made and remains unremedied for a period of \*\*\* after written notice to Licensee from Licensor;

(iii) if Licensee fails to perform or observe any other material covenant, term, condition or agreement contained in this Agreement and, if such failure is curable, such failure continues unremedied for a period of \*\*\* after written notice to Licensee from Licensor; or

(iv) Licensee institutes a Licensed Patent Challenge as set forth in Section 6.5(a).

(b) Notwithstanding the foregoing, if Licensee disputes the grounds for such termination in accordance with Section 7.4(a), Licensee shall provide written notice of the dispute to Licensor, and Licensor’s right to terminate this Agreement for cause in accordance with Section 7.4(a) shall be tolled, pending final resolution of such dispute pursuant to Section 9.2.

(c) Notwithstanding the foregoing, non-payment of the Issue Fee pursuant to Section 3.1 or non-payment of the Patent Reimbursement Amount pursuant to Section 6.2.1, in each case within \*\*\* of the applicable payment date shall result in Licensor having the right to terminate this Agreement immediately upon written notice to Licensee.

7.5 Licensee Termination. Licensee may, at its option, terminate this Agreement upon any material breach by Licensor under this Agreement, which Licensor fails to remedy within \*\*\* after notice thereof by Licensee. In addition, Licensee may terminate this Agreement at any time, for any business reason based on Licensee’s reasonable business judgment, upon at least \*\*\* prior written notice to Licensor.

7.6 Disposition of Licensee Developments. In the event of termination of this Agreement pursuant to Section 7.2, Section 7.3, or Section 7.4, Licensee shall \*\*\*.

7.7 Accrued Obligations. Expiration or termination of the Agreement will not release either party from any obligation that matured prior to the effective date of such expiration or termination. Nothing herein shall be construed to release Licensee from any obligations (including, without limitation and by way of example only, obligations (a) in respect of Earned Royalties for sales of Licensed Products that occurred on or before the termination date and (b) to pay or reimburse Licensor for Patenting Costs that relate to any period before the termination date).

7.8 Effects of Termination.

7.8.1 Termination of License. Upon a termination of this Agreement in its entirety under Section 7.4 or Section 7.5, Licensee’s rights to the Licensed Technology granted hereunder and all use thereof will terminate and any and all rights in the Licensed Technology will revert back to Licensor. Upon Licensor’s request and at Licensor’s sole option, Licensee will destroy or return all copies, except for the copies to be retained by Licensee’s legal counsel, of any media or materials that are the property of and previously received from Licensor, including all documentation, notes, plans, drawings, copies, samples and computer code.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

7.8.2 Effect on Sublicenses. Any Sublicense granted by Licensee under this Agreement shall, subject to the prior written consent of Licensor (which consent shall not be unreasonably withheld, conditioned or delayed and which consent shall not be required if the applicable Sublicensee is a Sublicensee approved by Licensor in accordance with Section 2.2 and is not then in breach of this Agreement ), survive termination of this Agreement, in which case such Sublicense shall be considered a direct license from Licensor to the applicable Sublicensee granting such Sublicensee a license to the Licensed Technology that was sublicensed to such Sublicensee in the sublicensed field, and such direct license will otherwise be on the terms and conditions of the Sublicense (to the extent applicable to the Licensed Technology); provided, however, that in the event of any inconsistencies between this Agreement and the Sublicense, this Agreement shall control.

7.8.3 \*\*\*.

7.8.4 Survival. Upon expiration or termination of this Agreement, Section 2.5 (Regulatory Affairs), Article 3 (Financial Consideration), Section 5.1 (Books and Records), Section 5.2 (Financial Audits), Section 5.3 (Product Reports), Section 6.2 (Patent Reimbursements), this Article 7 (Term and Termination), Article 8 (Confidential Information), Article 9 (Governing Law; Dispute Resolution), Article 10 (Indemnification and Insurance), Section 11.3 (Disclaimers) and 11.4 (Exclusion of Consequential and Other Indirect Damages), Article 12 (Notices), Article 13 (Assignment), Article 14 (Use of Name) and Article 23 (Miscellaneous Provisions) will, along with all defined terms used herein (whether defined in Article 1 (Definitions) or elsewhere in this Agreement) and any right, obligation or required performance of the parties in this Agreement which, by its express terms or nature and context is intended to survive termination or expiration of this Agreement, survive and remain in full force and effect.

Article 8  
CONFIDENTIALITY

8.1 Confidentiality Obligations. Each party (the “**Receiving Party**”) acknowledges that in connection with this Agreement it will gain access to Confidential Information of the other party (the “**Disclosing Party**”). As a condition to being provided with Confidential Information, the Receiving Party shall:

(a) not use the Disclosing Party's Confidential Information other than as necessary to exercise its rights and perform its obligations under this Agreement; and

(b) maintain the Disclosing Party's Confidential Information in strict confidence and, subject to Section 8.2, not disclose the Disclosing Party's Confidential Information without the Disclosing Party's prior written consent, provided, however, the Receiving Party may disclose the Confidential Information to its Representatives who:

(i) have a need to know the Confidential Information for purposes of the Receiving Party's performance, or exercise of its rights concerning the Confidential Information, under this Agreement;

(ii) have been apprised of this restriction; and

(iii) are themselves bound by written non-disclosure and non-use agreements at least as restrictive as those set forth in this Section 8.1, provided further that the Receiving Party shall be responsible for ensuring its Representatives' compliance with, and shall be liable for any breach by its Representatives of, this Section 8.1.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

The Receiving Party shall use reasonable care, at least as protective as the efforts it uses for its own confidential information, to safeguard the Disclosing Party's Confidential Information from use or disclosure other than as permitted hereby.

8.2 Exceptions. If the Receiving Party becomes legally compelled to disclose any Confidential Information, the Receiving Party shall:

(a) provide prompt written notice to the Disclosing Party so that the Disclosing Party may seek a protective order or other appropriate remedy or waive its rights pursuant to Article 12; and

(b) disclose only the portion of Confidential Information that it is legally required to furnish.

If a protective order or other remedy is not obtained, or the Disclosing Party waives compliance in accordance with Article 12 and Article 21, the Receiving Party shall, at the Disclosing Party's expense, use reasonable efforts to obtain assurance that confidential treatment will be afforded the Confidential Information.

8.3 Confidential Terms. Notwithstanding anything to the contrary herein, the parties may disclose the terms and existence of this Agreement to potential or actual investors, acquirers, Sublicensees, collaboration partners, consultants, advisors and others on a reasonable need to know basis subject to customary confidentiality restrictions, or as required by securities or other applicable Laws.

Article 9

GOVERNING LAW; DISPUTE RESOLUTION

9.1 Governing Law. This Agreement and all related documents, and all matters arising out of or relating to this Agreement, are governed by, and construed in accordance with, the laws of the State of Ohio, United States of America, without regard to the conflict of laws' provisions thereof to the extent such principles or rules would require or permit the application of the laws of any jurisdiction other than those of the State of Ohio.

9.2 Dispute Resolution.

9.2.1 Exclusive Dispute Resolution Mechanism. The parties shall resolve any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity hereof (each, a “**Dispute**”), under the provisions of this Section 9.2. The procedures set forth in this Section 9.2 shall be the exclusive mechanism for resolving any Dispute that may arise from time to time , subject to Section 23.7.

9.2.2 Good Faith Negotiations. If a party believes that a Dispute exists, then such party (the “**Declaring Party**”) shall provide notice of such Dispute to the other party (the “**Notice**”), which Notice shall specify the nature and cause of the Dispute and the action that the Declaring Party deems necessary to resolve such Dispute. Following receipt of the Notice, the parties shall use good faith efforts to resolve the Dispute, including making personnel with appropriate decision-making authority available to the other party to discuss resolution of the Dispute. If a Dispute is not resolved within \*\*\* of the date of the non-Declaring Party's receipt of the Notice, then the Dispute shall be submitted to mandatory, final and binding arbitration before the American Arbitration Association, in accordance with the then-current rules of the American Arbitration Association, as modified herein.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

9.2.3 Arbitration. The parties shall use a panel of three arbitrators. The Declaring Party shall select one arbitrator, and the other party shall select a second arbitrator, and the two arbitrators so selected shall select a third arbitrator. The three arbitrators shall hear the Dispute. Such arbitrators shall be knowledgeable in intellectual property law and related matters. The arbitrators shall make each determination in a manner that is consistent with this Agreement, including the parties’ intent as expressed herein. Without limiting the foregoing, the parties agree that the arbitrators are empowered to make determinations regarding the reasonableness of a party’s acts or omissions. All decisions of the arbitrators shall be binding upon the parties. Each party shall be solely responsible for its own attorneys’ fees and expenses, legal expenses and witness fees and expenses. Any other usual and customary expenses incurred by the arbitrators or the expense of such arbitration proceeding shall be equally divided between the parties, irrespective of the outcome of such proceeding. The arbitration will be conducted in Cleveland, Ohio. The arbitrators are to apply the laws of the State of Ohio, without regard to its conflict of laws’ provisions. The parties agree that any award, order, or judgment pursuant to the arbitration is final and may be entered and enforced in any court of competent jurisdiction. The parties agree that all aspects of the dispute resolution process, including the arbitration, shall be conducted in confidence. The parties agree that all statements made in connection with informal dispute resolution efforts shall not be considered admissions or statements against interest by any party. The parties further agree that they will not attempt to introduce such statements at any later trial, arbitration or mediation between the parties.

9.3 Waiver of Jury Trial. Each party irrevocably and unconditionally waives any right it may have to a trial by jury for any legal action arising out of or relating to this Agreement or the transactions contemplated hereby.

Article 10  
INDEMNIFICATION AND INSURANCE

10.1 Indemnification

10.1.1 Licensee Indemnification. Subject to Section 10.1.3, Licensee will indemnify, defend and hold harmless Licensor and its respective trustees, directors, officers, medical and professional staff, employees, students, and agents and their respective successors, heirs, and assigns (each a “**Licensor Indemnitee**”), against all Losses arising from any third party claim, suit, action or other proceeding (each, an “**Action**”) which may be made or instituted against any Licensor Indemnitee related to, arising out of or resulting from (a) Licensee's material breach of any representation, warranty, covenant or obligation under this Agreement, (b) use by Licensee or its Sublicensee or any of the foregoing Persons’ respective transferees of Licensed Technology, (c) any use, sale, transfer or other disposition by Licensee or its Sublicensee or any of the foregoing Persons' respective transferees of Licensed Products or any other products made by use of Licensed Technology, or (d) (i) Licensee’s enforcement or defense of the Licensed Patents or (ii) prosecution actions in respect of the Licensed Patents, to the extent such prosecution actions were taken at the request of or under the direction or guidance of Licensee, except to the extent any such Action arises from any matter for which Licensor is obligated to provide indemnification pursuant to Section 10.1.2.

10.1.2 Licensor Indemnification. Subject to Section 10.1.3, to the extent allowed under applicable Laws, Licensor will indemnify, defend and hold harmless Licensee and its respective directors, officers, employees, consultants, and agents and their respective successors, heirs, and assigns (each a “**Licensee Indemnitee**”), against all Losses arising from any Action which may be made or instituted against any Licensee Indemnitee related to, arising out of or resulting from (a) Licensor's material breach of any representation, warranty, covenant or obligation under this Agreement, or (b) a Licensor Indemnitee’s negligence, willful misconduct, or breach of any applicable Law, except to the extent any such Action arises from any matter for which Licensee is obligated to provide indemnification pursuant to Section 10.1.1.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

10.1.3 Indemnification Procedure. An Indemnitee (whether a Licensor Indemnitee or a Licensee Indemnitee) that intends to claim indemnification under this Section 10.1 will give notice to the indemnifying party of any Action which might be covered by this Section 10.1. The indemnifying party shall immediately take control of the defense and investigation of the Action, including selection of counsel reasonably acceptable to the Indemnitee, at the indemnifying party's sole cost and expense; provided, however, that the indemnifying party will not, without the prior written consent of the Indemnitee, settle or consent to the entry of any judgment with respect to such Action (a) that does not release the Indemnitee from all liability with respect to such Action, or (b) that may adversely affect the Indemnitee or under which the Indemnitee would incur any obligation or liability, other than one as to which the indemnifying party has an indemnity obligation hereunder. The Indemnitee agrees to cooperate and provide reasonable assistance to such defense at the indemnifying party's expense. The Indemnitee at all times reserves the right to select and retain counsel of its own at its own expense to defend its interests, provided that the indemnifying party will remain in control of the defense. The Indemnitee's failure to perform any obligations under this Section 10.1.3 shall not relieve the indemnifying party of its obligation under Section 10.1 except to the extent that the indemnifying party can demonstrate that it has been materially prejudiced as a result of the failure.

10.2 Insurance.

(a) Prior to using, selling, transferring or otherwise disposing of any Licensed Product (including for the purpose of obtaining regulatory approvals), Licensee shall, at its sole cost and expense, obtain, pay for and maintain commercial general liability and professional liability (Errors and Omissions) insurance in commercially reasonable and appropriate amounts that provides product liability coverage concerning the Licensed Products, including without limitation coverage for human trials, and contractual liability coverage for Licensee's defense and indemnification obligations under this Agreement. To the extent any insurance coverage required under this Section 10.2 is purchased on a "claims-made" basis, such insurance shall cover all prior acts of Licensee during the Term, and be continuously maintained until at least \*\*\* beyond the expiration or termination of the Term, or Licensee shall purchase "tail" coverage, effective upon termination of any such policy or upon termination or expiration of the Term, to provide coverage for at least \*\*\* from the occurrence of either such event. Promptly upon Licensor's request, Licensee will present evidence to Licensor that the coverage is being maintained. In addition, Licensee will provide Licensor with at least \*\*\* prior written notice of any material change in or cancellation of the insurance coverage.

(b) Licensee shall insert this Section 10.2 in any Sublicense, with the name of the Sublicensee substituted for the name of Licensee therein.

10.3 Lapse of Coverage. If Licensor elects to terminate this Agreement pursuant to (and subject to the cure period set forth in) Section 7.4 for any breach of Section 10.2, then such termination shall occur and become effective pursuant to Section 7.4. Nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. Notwithstanding the foregoing, in the \*\*\* period subsequent to the date of such a termination of this Agreement pursuant to Section 7.4, to the extent that such rights are still available for licensing, Licensee shall have the right to reinstate the effectiveness of this Agreement by obtaining the required insurance, whereupon this Agreement shall automatically become effective as of the date of reinstatement of said insurance and shall remain in full force and effect without any further action of the parties.

**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

Article 11  
REPRESENTATIONS AND WARRANTIES

11.1 Representations and Warranties of Licensee. Licensee represents and warrants to Licensor as follows:

(a) to the Licensee’s knowledge, Licensee has not received any notice or threat of any claim, suit, action or proceeding, and has no knowledge or reason to know of any information, that could: (i) invalidate or render unenforceable any claim of any Licensed Patent; (ii) prove that the Licensed Products are not covered by any claim of any Licensed Patent; or (iii) cause any claim of any Licensed Patent to fail to issue or be materially limited or restricted as compared with its currently pending scope;

(b) to the Licensee’s knowledge, the execution and performance of Licensee’s obligations under this Agreement does not conflict with, cause a default under, or violate any existing contractual obligation that may be owed by Licensee to any third party;

(c) all Licensed Products will be manufactured in all material respects in accordance with applicable Laws, including, without limitation, all applicable Laws of the FDA and any other applicable Regulatory Authority;

(d) Licensee is a corporation duly organized, validly existing and in good standing under the laws of the state of its jurisdiction of organization;

(e) to the Licensee’s knowledge, Licensee has all requisite corporate power and authority, and the legal right, to execute and deliver this Agreement and to perform its obligations hereunder;

(f) to the Licensee’s knowledge, the execution and delivery of this Agreement by Licensee and the performance of its obligations hereunder have been duly authorized by all necessary corporate action in accordance with all applicable Laws. Licensee has duly executed and delivered this Agreement; and

(g) this Agreement is a valid, legal and binding obligation of Licensee, enforceable against Licensee in accordance with its terms.

11.2 Representations and Warranties of Licensor. Licensor represents and warrants to Licensee as follows:

(a) to Licensor’s knowledge, it is the exclusive owner of all rights, title and interests in the Licensed Patents and has the right, power and authority to grant Licensee the licenses in Section 2.1 and it does not own any patents or patent applications other than the Licensed Patents the claims of which would dominate any practice of the Licensed Technology in the Fields.

(b) to Licensor’s knowledge, the execution and performance of Licensor’s obligations under this Agreement do not conflict with, cause a default under, or violate any existing contractual obligation that may be owed by Licensor to any third party.

(c) Licensor is a nonprofit corporation duly organized, validly existing and in good standing and has all requisite power and authority to execute and deliver, and perform its obligations under, this Agreement;



**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

- (d) to Licensor’s knowledge, the execution and performance of Licensor’s obligations under this Agreement do not conflict with, cause a default under, or violate any existing contractual obligation that may be owed by Licensor to any third party;
- (e) this Agreement is a valid, legal and binding obligation of Licensor, enforceable against Licensor in accordance with its terms; and
- (f) as of the Effective Date, to Licensor’s knowledge, there is no infringement claim pending or threatened in writing against Licensor related to any of the Licensed Patents.

For purposes of this Section 11.2, “knowledge” means the actual knowledge of Vincent K. Tuohy and individuals employed by Licensor in the group known as “Cleveland Clinic Innovations” as of the Effective Date. For purposes of this Agreement, “Cleveland Clinic Innovations” means Tony Giordano and Greg Frykman.

**11.3 Disclaimer of Representations and Warranties.**

(a) Except as expressly provided herein, Licensee acknowledges and agrees that all rights licensed by Licensor hereunder are licensed “as is” and without any representation, indemnification or warranty with respect to possible infringement of third party rights. Except as expressly provided herein, nothing in this Agreement shall be construed as (i) a warranty or representation by Licensor as to the validity or scope of any Licensed Patents, (ii) a warranty or representation that anything made, used, imported, developed, promoted, offered for sale, sold, or otherwise disposed of under any license granted in this Agreement does not or will not infringe patents, trade secrets, copyrights or other intellectual or proprietary rights of third parties; (iii) a representation or warranty of operability or that development of a commercial products is possible; (iv) an obligation to bring or prosecute actions or suits against third parties for infringement; (v) conferring the right to use in advertising, publicity or otherwise any trademark, trade name, or names, or any contraction, abbreviation, simulation or adaptation thereof of Licensee or Licensor; (vi) conferring by implication, estoppel or otherwise any license or rights under any patents of Licensor other than the Licensed Patents; and (vii) any other representations or warranties, either express or implied, unless specified in this Agreement. Except as expressly provided herein, the furnishing of Confidential Information by either party shall not be interpreted to convey any grant of rights, titles, interests, options or licenses to the receiving party under any intellectual property rights owned or controlled by such party, other than the license under the Licensed Technology.

(b) EXCEPT AS EXPRESSLY PROVIDED HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN, ORAL, EXPRESS, IMPLIED STATUTORY OR OTHERWISE, CONCERNING THE VALIDITY, ENFORCEABILITY AND SCOPE OF THE LICENSED PATENTS, THE ACCURACY, COMPLETENESS, SAFETY, USEFULNESS FOR ANY PURPOSE OR, LIKELIHOOD OF SUCCESS (COMMERCIAL, REGULATORY OR OTHER) OF THE LICENSED PRODUCTS, LICENSED KNOW-HOW AND ANY OTHER TECHNICAL INFORMATION, TECHNIQUES, MATERIALS, METHODS, PRODUCTS, PROCESSES OR PRACTICES AT ANY TIME MADE AVAILABLE BY LICENSOR INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT AND WARRANTIES ARISING FROM A COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OR TRADE PRACTICE. WITHOUT LIMITATION TO THE FOREGOING, LICENSOR SHALL HAVE NO LIABILITY WHATSOEVER TO LICENSEE OR ANY OTHER PERSON FOR OR ON ACCOUNT OF ANY INJURY, LOSS, OR DAMAGE, OF ANY KIND OR NATURE, SUSTAINED BY, OR ANY DAMAGE ASSESSED OR ASSERTED AGAINST, OR ANY OTHER LIABILITY INCURRED BY OR IMPOSED ON LICENSEE OR ANY OTHER PERSON, ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM: (X) THE MANUFACTURE, USE, OFFER FOR SALE, SALE, OR IMPORT OF A LICENSED PRODUCT, OR THE PRACTICE OF THE LICENSED PATENTS; (Y) THE USE OF OR ANY ERRORS OF OMISSIONS IN ANY KNOW-HOW, TECHNICAL INFORMATION, TECHNIQUES, OR PRACTICES DISCLOSED BY LICENSOR; OR (Z) ANY ADVERTISING OR OTHER PROMOTIONAL ACTIVITIES CONCERNING ANY OF THE FOREGOING.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

11.4 Exclusion of Consequential and Other Indirect Damages. EXCEPT FOR DAMAGES ARISING FROM A BREACH OF ARTICLE 8, FRAUD, WILLFUL MISCONDUCT, OR GROSS NEGLIGENCE, OR AS MAY BE PAYABLE PURSUANT TO A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 10, IN NO EVENT WILL EITHER PARTY, OR THE LICENSOR INDEMNITEES OR THE LICENSEE INDEMNITEES, BE LIABLE TO THE OTHER PARTY FOR ANY INJURY TO OR LOSS OF GOODWILL, REPUTATION, BUSINESS, PRODUCTION, REVENUES, PROFITS, ANTICIPATED PROFITS, CONTRACTS OR OPPORTUNITIES (REGARDLESS OF HOW THESE ARE CLASSIFIED AS DAMAGES), OR FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, PUNITIVE OR ENHANCED DAMAGES WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, PRODUCT LIABILITY OR OTHERWISE (INCLUDING THE ENTRY INTO, PERFORMANCE OR BREACH OF THIS AGREEMENT), REGARDLESS OF WHETHER SUCH LOSS OR DAMAGE WAS FORESEEABLE OR THE PARTY AGAINST WHOM SUCH LIABILITY IS CLAIMED HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS OR DAMAGE, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE.

Article 12  
NOTICES

Any payment, notice or other communication to be given pursuant to the provisions of this Agreement shall be in writing by means of a letter or electronic mail directed:

***If to Licensor:***

*General correspondence to:*

The Cleveland Clinic Foundation  
9500 Euclid Avenue, Mailstop GCIC10  
Cleveland, OH 44195  
Attn: CCF Innovations – Executive Director  
Email: giordat@ccf.org  
With a copy to: cclicense@ccf.org

*Payments to:*

\*\*\*

*With copies to:*

Law Department  
The Cleveland Clinic Foundation  
3050 Science Park Drive, AC321  
Beachwood, OH 44122  
Attn: Chief Legal Counsel, CC Innovations  
Email: legalcontracts@ccf.org  
With a copy to: cicarej@ccf.org

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

***If to Licensee:***

*General correspondence to:*

Anixa Biosciences, Inc.  
3150 Almaden Expressway, Suite 250  
San Jose, CA 95118  
Attn: Amit Kumar, CEO  
Email: ak@anixa.com

Notices sent in accordance with this Section 12 shall be deemed effectively given: (a) when received, if sent by a nationally or internationally recognized courier (receipt requested); or (b) on the date sent by e-mail (with confirmation of transmission), if sent during normal business hours of the recipient, and on the next business day if sent after normal business hours of the recipient.

Article 13  
ASSIGNMENT

This Agreement will be binding upon and will inure to the benefit of each party and each party’s respective transferees, successors and assigns. Notwithstanding the foregoing, Licensee may not transfer, delegate or assign this Agreement or any rights or obligations hereunder (for clarity, excluding the grant of Sublicenses approved by Licensor in accordance with Section 2.2) without the prior written consent of Licensor (not to be unreasonably withheld, conditioned or delayed). For purposes of this Article 13, transfer or assignment that will require such prior written consent will include any express assignment, Change in Control of Licensee, or other transfer or assignment by operation of law; provided that such consent will not be required in the case of transfer or assignment in connection with a Change in Control in which the successor entity is a Sublicensee approved by Licensor in accordance with Section 2.2. Upon written request, Licensee may obtain Licensor’s prior written consent to the transfer or assignment of this Agreement to a particular entity in connection with a Change in Control in advance of the negotiation of such Change in Control. Any such request shall identify the potential successor entity(ies), but shall not be required to contain any terms or conditions of the potential Change in Control. Licensor shall respond to any such request within \*\*\* of receipt. Any failure by Licensor to respond to any such request within such period shall be deemed to constitute Licensor’s prior written consent to the transfer or assignment of this Agreement to the entity(ies) identified in such request. In addition, any such consent given (or deemed to have been given) by Licensor shall remain in effect with respect to each potential successor entity for \*\*\* after the effective date of such consent and shall apply to the applicable entity(ies) identified in such request and any Affiliates thereof.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

Article 14  
USE OF NAME

Licensee shall not use the name, logo, likeness, trademarks, or image of Licensor for advertising, marketing, endorsement or any other purposes without the specific prior written consent of an authorized representative of Licensor as to each such use. Licensee shall not make any public announcements, make any public statements, issue any press releases or otherwise communicate with any news media in respect of this Agreement or the transactions contemplated hereby without the specific prior written consent of an authorized representative of Licensor. Licensee shall not be required to attain consent under this Article 14 for use that is pursuant to applicable law or regulation, including Licensee's obligations under disclosure rules of the Securities and Exchange Commission (SEC). Licensor's specific prior written consent to one use shall apply only to other uses of substantially similar form and content (e.g. various iterations of investor presentations) but not to any other uses. Notwithstanding anything to the contrary contained herein, Licensor shall have the right to withdraw any consent previously provided (e.g., if Licensor has previously consented to Licensee's use of Licensor's name and logo on Licensee's website or in investor presentations). For clarity, this Article 14 shall not restrict Licensee (or its Affiliates or Sublicensees) from publicly disclosing information regarding the status of the development, or manufacture or commercialization of any Licensed Product, provided that any such disclosure does not use the name, logo, likeness, trademark or image of Licensor.

Article 15  
EXPORT CONTROLS; REGULATORY CLEARANCE

15.1 Export Controls. Neither Licensee nor any of its Sublicensees shall, directly or indirectly, export (including any "deemed export"), nor re-export (including any "deemed re-export") the Licensed Products (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of any applicable U.S. Laws. Licensee and each Sublicensee shall include a provision identical in substance to this Section 15.1 in its agreements with its Sublicensees, third party wholesalers, distributors, customers and end-users requiring that these Persons comply with all applicable U.S. Laws, including all applicable U.S. export Laws. For the purposes of this Section 15.1, the terms "deemed export" and "deemed re-export" have the meanings set forth in Section 734.2(b)(2)(ii) and Section 734.2(b)(4), respectively, of the Export Administration Regulations (EAR) (*15 CFR §§ 734.2(b)(2)(ii) and 734.2(b)(4)*).

15.2 Regulatory Clearances. Licensee shall, at Licensee's expense, comply with all regulations and safety standards concerning Licensed Products developed and commercialized by or under the authority of Licensee and obtain all necessary governmental approvals for the development, production, distribution, sale and use of Licensed Products developed and commercialized by or under the authority of Licensee, including any safety or clinical studies. Licensee shall have responsibility for and provide suitable warning labels, packaging and instructions as to the use for such Licensed Products.

Article 16  
MARKING

Licensee shall and shall require any Sublicensee to comply with any applicable patent marking provisions of 35 USC § 287(a) by marking all Licensed Products with the word "patent" or the abbreviation "pat." and either the numbers of the relevant Licensed Patents or a web address that is freely accessible to the public and that associates the Licensed Products with the relevant Licensed Patents. Licensee shall include in all Sublicenses a patent marking requirement substantially identical to this Article 16. Licensee shall and shall require any Sublicensee to also comply with the patent marking laws of the relevant countries in the Territory.

Article 17  
SEVERABILITY

If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or other provision is invalid, illegal or unenforceable, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

Article 18

ANTI-KICKBACK AND STARK LAW

Licensee agrees to comply with all applicable Laws. Without limiting the foregoing, by entering into this Agreement, the Licensee will comply with all applicable laws, rules and regulations including (i) the federal anti-kickback statute (42 U.S.C. §1320a-7b) and the related safe harbor regulations; and (ii) the Limitation on Certain Physician Referrals, also referred to as the “Stark Law” (42 U.S.C. 1395nn). Accordingly, no part of any consideration paid hereunder is a prohibited payment for the recommendation of or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business. In the event that any part of this Agreement is determined to violate federal, state, or local laws, rules or regulations, the Parties agree to negotiate in good faith revisions to the provision or provisions that are in violation.

Article 19

CONFLICT OF INTEREST

Licensor maintains and adheres to a Conflict of Interest Policy. In that connection Licensee represents that no Licensor employees, officers, trustees or directors are consultants, employees, officers or directors or, to the best of Licensee’s knowledge, owners of Licensee or any of its Affiliates or serve on any boards or committees of or in any advisory capacity with Licensee or any of its Affiliates, except as disclosed in Exhibit D attached hereto. Any payments made to such parties listed on Exhibit D are at fair market value for services rendered

Article 20

HEADERS

The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

Article 21

BENEFIT AND WAIVER

The failure of either party to comply with any obligation, covenant, agreement or condition under this Agreement may be waived by the party entitled to the benefit thereof only by a written instrument signed by the party on granting such waiver, but such waiver or failure to insist upon strict compliance with such obligation, covenant, agreement or condition will not operate as a waiver of, or estoppel with respect to, any subsequent or other failure. The failure of any party to enforce at any time any of the provisions of this Agreement will in no way be construed to be a waiver of any such provision, nor in any way to affect the validity of the Agreement or any part thereof or the right of any party thereafter to enforce each and every such provision. No waiver of any breach of such provisions will be held to be waiver of any other or subsequent breach.

**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

Article 22  
ENTIRE AGREEMENT

This Agreement (together with any exhibits, schedules or appendices attached hereto) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous or contemporaneous negotiations, commitments, and writings with respect to such subject matter. Neither party shall be obligated by any undertaking nor representation regarding the subject matter hereof other than those expressly stated herein or as may be subsequently agreed to by the parties hereto in writing.

Article 23  
MISCELLANEOUS PROVISIONS

23.1 Amendment. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each party.

23.2 Further Assurances. Each party shall, upon the request of the other party, promptly execute such documents and take such further actions as may be necessary to give full effect to the terms of this Agreement.

23.3 Debarment. Licensee hereby represents and warrants that it has not been debarred, suspended, excluded or otherwise determined to be ineligible to participate in federal healthcare programs or federal procurement and non-procurement programs (collectively, “**Debarred**”) and Licensee agrees not to engage or assign any employee, agent or contractor (“**Agent**”) to perform services under this Agreement who has been Debarred. Licensee acknowledges that Licensor shall have the right to terminate this Agreement in accordance with Section 7.4 in the event that Licensee or an Agent is Debarred and not promptly removed. Accordingly, Licensee shall provide Licensor with immediate notice if during the Term of this Agreement Licensee (a) receives notice of action or threat of action with respect to its Debarment or (b) becomes Debarred.

23.4 Independent Contractors. Both parties are independent contractors under this Agreement. Nothing contained in this Agreement will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

23.5 Tax Exempt Status. The parties recognize that Licensor is a non-profit, tax-exempt organization and agree that this Agreement will take into account and be consistent with Licensor’s tax-exempt status. If any part or all of this Agreement is determined to jeopardize the overall tax-exempt status of Licensor and/or any of its exempt Affiliates, the parties will negotiate in good faith an amendment of this Agreement pursuant to Article 17 so as to address such tax consideration while effecting the original intent of the parties as closely as possible in a mutually acceptable manner.

23.6 Waiver of Automatic Stay. In the event Licensee is the subject of any voluntary or involuntary proceeding under the Bankruptcy Code, Licensee hereby unconditionally and irrevocably agrees that Licensor is immediately entitled, without notice, demand or any other action, to relief from the automatic stay so as to allow Licensor to enforce its rights and remedies under this Agreement, or at law and in equity under applicable state law. Licensee hereby consents to the immediate lifting, without notice, demand or any other action, of any such automatic stay and agrees that it shall not, in any manner, contest or otherwise delay any motion filed by Licensor for relief from the automatic stay. Licensor's enforcement of this stay waiver is subject to the approval of the bankruptcy court in which the case is then pending.

**Redactions with respect to certain portions hereof denoted with “\*\*\*\*”**

23.7 Equitable Relief. Each party acknowledges that a breach by the other party of this Agreement may cause the non-breaching party irreparable harm, for which an award of damages would not be adequate compensation and, in the event of such a breach or threatened breach, the non-breaching party shall be entitled to seek equitable relief, including in the form of a restraining order, orders for preliminary or permanent injunction, specific performance and any other relief that may be available from any court, and the parties hereby waive any requirement for the securing or posting of any bond or the showing of actual monetary damages in connection with such relief. These remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available under this Agreement at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

23.8 Counterparts. This Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one party but all such counterparts taken together will constitute one and the same agreement. A signed copy of this Agreement delivered by e-mail to which a PDF copy is attached shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

*[SIGNATURE PAGE FOLLOWS]*

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized representatives effective as of the Effective Date.

**The Cleveland Clinic Foundation**

By /s/ Steven C. Glass  
Name Steven C. Glass  
Title Chief Financial Officer

**Anixa Biosciences, Inc.**

By /s/ Michael J. Catelani  
Name Michael J. Catelani  
Title COO & CFO



**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

**Appendix A**  
**LICENSED TECHNOLOGY**

*Licensed Patents:*

\*\*\*

*Licensed Know-how:*

\*\*\*

Appendix A-1

---

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

**Exhibit A**  
**DEVELOPMENT PLAN**

To be provided pursuant to Section 5.7.

A-1

---

Redactions with respect to certain portions hereof denoted with “\*\*\*”

**Exhibit B  
FORM OF ROYALTY REPORT**

Licensee/Sublicensee: \_\_\_\_\_

Agreement Effective Date: \_\_\_\_\_

Period Reported: \_\_\_\_\_

Product name or Catalog number	Description	Activity Type (External Sales / Internal Sales)	Country	Sold to:	Number of units sold	Total Quarterly Gross Sales	Less Allowable Deductions	Net Sales	Royalty Rate	Other Income (including Sublicensing Revenue)	Total Due
			(US, Canada, Japan, etc.)	(Note CCF Sales)							
Total:	Total:										\$ -

<b>Total Royalties Due</b>	\$	-
Prior Quarterly Payments:	\$	-
Minimum Annual	\$	-
Cumulative Net Sales:		

**Exhibit C**  
**FORM OF DEVELOPMENT REPORT**

Date development plan initiated and time period covered by this report.

Development Report.

- Activities completed since last report including the object and parameters of the development, when initiated, when completed, a summary of the data collected, and the results.
- Activities currently under investigation, *i.e.*, ongoing activities including object and parameters of such activities when initiated, and projected date of completion.

Future Development Activities.

- Activities to be undertaken before next report including the type and object of any studies conducted and their projected starting and completion dates.
- Estimated total development time remaining before a product will be commercialized.

Changes to initial Development Plan.

- Reasons for change.
- Variables that may cause additional changes.

Items to be provided if applicable:

- Information relating to Licensed Product that has become publicly available, *e.g.*, published Sections, competing products, patents, etc.
- Development work being performed by third parties other than Licensee to include name of third party, reasons for use of third party, planned future uses of third parties including reasons why and type of work.
- Update of competitive information trends in industry, government compliance (if applicable) and market plan.
- \*\*\* estimate of Net Sales

**Redactions with respect to certain portions hereof denoted with “\*\*\*”**

**Exhibit D**  
**CONFLICT OF INTEREST**

None.

**AMENDMENT 1 TO THE COLLABORATION AGREEMENT  
BETWEEN  
CERTAINTY THERAPEUTICS, INC.  
AND  
H. LEE MOFFITT CANCER CENTER AND RESEARCH INSTITUTE, INC.**

Moffitt Agreement Identifier: Anixa-CERTainty Contract (Conejo-Garcia) 17-0173  
Project Title: Development of CAR-T/CER-T Therapies for Ovarian and Prostate Cancer  
Moffitt Principle Investigator: Dr. Jose Conejo-Garcia

The Agreement described above was previously entered into on November 17, 2017 (hereinafter "Effective Date") by and between H. Lee Moffitt Cancer Center and Research Institute, Inc. a non-profit Florida corporation organized pursuant to Section 1004.43, Florida Statutes, whose address is 12902 Magnolia Drive, Tampa, Florida 33612 ("Moffitt") and Certainty Therapeutics, Inc., a corporation duly organized under the laws of Delaware whose address is 3150 Almaden Expressway, Suite 250, San Jose, California 95118 (hereinafter "Company"). Moffitt and Company are hereinafter referred to individually as "Party" and collectively as "Parties."

WHEREAS, Moffitt requests an extension of the Agreement end date from November 17, 2019 to November 17, 2020; and

WHEREAS, Company agrees to Moffitt's extended participation in the investigation set forth in the Research Plan attached as Exhibit B to the original Agreement; and

WHEREAS, Moffitt and Company agree this amendment will continue to be governed by the Research Plan and milestone payment schedule defined in the original Agreement.

WHEREAS, Moffitt and Company agree to this modification as set forth by procedures described in Section 13.9 of the original Agreement.

NOW, THEREFORE, in consideration of the foregoing recitals, which are incorporated herein as covenants, and the mutual promises herein made and exchanged, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Company and Moffitt agree to the following modification:

ARTICLE 7 Term and Termination.

7.1 This Agreement will commence as of the Effective Date set forth in the first paragraph of this Agreement and unless terminated otherwise as provided herein, this Agreement will expire thirty-six (36) months from such date, unless extended upon mutual written agreement of the Parties ("Term").

CERTAINTY THERAPEUTICS, INC.

H. LEE MOFFITT CANCER CENTER  
AND RESEARCH INSTITUTE, INC.

BY: /s/ Amit Kumar  
Name: Amit Kumar  
Title: Chief Executive Officer (CEO)

BY: /s/ Margaret J. Fonner  
Name: Margaret J. Fonner  
Title: Director, Office of Sponsored Research

CERTIFICATION

I, Dr. Amit Kumar, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Anixa Biosciences, 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.

/s/ Dr. Amit Kumar

Dr. Amit Kumar  
Chairman, President and  
Chief Executive Officer  
(Principal Executive Officer)

September 6, 2019



CERTIFICATION

I, Michael J. Catelani, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Anixa Biosciences, 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.

/s/ Michael J. Catelani

Michael J. Catelani  
Chief Operating Officer and  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)

September 6, 2019

Statement of Chief Executive Officer  
Pursuant to Section 1350 of Title 18 of the United States Code

Pursuant to Section 1350 of Title 18 of the United States Code, the undersigned, Dr. Amit Kumar, the Chairman, President and Chief Executive Officer of Anixa Biosciences, Inc., hereby certifies that:

1. The Company's Form 10-Q Quarterly Report for the period ended July 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Dr. Amit Kumar

Dr. Amit Kumar  
Chairman, President and  
Chief Executive Officer  
(Principal Executive Officer)

September 6, 2019

Statement of Chief Financial Officer  
Pursuant to Section 1350 of Title 18 of the United States Code

Pursuant to Section 1350 of Title 18 of the United States Code, the undersigned, Michael J. Catelani, the Chief Operating Officer and Chief Financial Officer of Anixa Biosciences, Inc., hereby certifies that:

1. The Company's Form 10-Q Quarterly Report for the period ended July 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael J. Catelani  
\_\_\_\_\_  
Michael J. Catelani  
Chief Operating Officer and  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)

September 6, 2019