U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)
☒ QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: December 31, 2018

OR

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

For the transition period from _____ to _____

Commission File Number 001-38174

Citius Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**27-3425913**
(*State or other jurisdiction of incorporation or organization*)	(*IRS Employer Identification No.*)

11 Commerce Drive, First Floor, Cranford, NJ 07016
(*Address of principal executive offices and zip code*)

(908) 967-6677
(*Registrant's telephone number, including area code*)

(*Former name, former address and former fiscal year, if changed since last report*)

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 filed 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or 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, a smaller reporting company or an emerging growth company.

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

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

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

As of February 8, 2019, there were 18,520,360 shares of common stock, $0.001 par value, of the registrant issued and outstanding.

Citius Pharmaceuticals, Inc.
FORM 10-Q
TABLE OF CONTENTS
December 31, 2018

EXPLANATORY NOTE

In this Quarterly Report on Form 10-Q, and unless the context otherwise requires, the "Company," "we," "us" and "our" refer to Citius Pharmaceuticals, Inc. and its wholly owned subsidiaries, Citius Pharmaceuticals, LLC and Leonard-Meron Biosciences, Inc., taken as a whole.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in this report and in other documents which we file with the Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to:

- our ability to raise funds for general corporate purposes and operations, including our clinical trials;
- the cost, timing and results of our clinical trials;
- our ability to obtain and maintain required regulatory approvals for our product candidates;
- the commercial feasibility and success of our technology;
- our ability to recruit qualified management and technical personnel to carry out our operations; and
- the other factors discussed in the "Risk Factors" section of our most recent Annual Report on Form 10-K and elsewhere in this report.

Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the filing date of this report.

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	December 31, 2018	September 30, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 7,041,473	$ 9,184,003
Other receivables	—	818,343
Prepaid expenses	46,623	57,732
Total Current Assets	7,088,096	10,060,078
Property and Equipment, Net	1,248	1,483
Other Assets:		
Deposits	2,167	2,167
In-process research and development	19,400,000	19,400,000
Goodwill	1,586,796	1,586,796
Total Other Assets	20,988,963	20,988,963
Total Assets	$ 28,078,307	$ 31,050,524
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,083,432	$ 1,573,444
Accrued expenses	200,430	181,657
Accrued compensation	1,381,415	1,198,915
Accrued interest – related parties	61,857	57,854
Notes payable – related parties	172,970	172,970
Total Current Liabilities	3,900,104	3,184,840
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock – $0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock – $0.001 par value; 200,000,000 shares authorized; 17,798,791 and 16,198,791 shares issued and outstanding at December 31, 2018 and September 30, 2018, respectively	17,799	16,199
Additional paid-in capital	68,292,972	68,107,323
Accumulated deficit	(44,132,568)	(40,257,838)
Total Stockholders' Equity	24,178,203	27,865,684
Total Liabilities and Stockholders' Equity	$ 28,078,307	$ 31,050,524

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE MONTHS ENDED DECEMBER 31, 2018 AND 2017
(Unaudited)

	Three Months Ended	
	December 31, 2018	December 31, 2017
Revenues	$ —	$ —
Operating Expenses		
Research and development	2,113,101	606,521
General and administrative	1,588,124	2,346,240
Stock-based compensation – general and administrative	171,249	290,021
Total Operating Expenses	3,872,474	3,242,782
Operating Loss	(3,872,474)	(3,242,782)
Other Income (Expense)		
Interest income	1,747	—
Interest expense	(4,003)	(3,384)
Total Other Expense, Net	(2,256)	(3,384)
Loss before Income Taxes	(3,874,730)	(3,246,166)
Income tax benefit	—	—
Net Loss	$ (3,874,730)	$ (3,246,166)
Net Loss Per Share - Basic and Diluted	$ (0.22)	$ (0.38)
Weighted Average Common Shares Outstanding		
Basic and diluted	17,764,008	8,605,046

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS ENDED DECEMBER 31, 2018
(Unaudited)

	Preferred Stock	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
		Shares	Amount			
Balance, October 1, 2018	$ —	16,198,791	$ 16,199	$ 68,107,323	$ (40,257,838)	$ 27,865,684
Issuance of common stock upon exercise of warrants	—	1,600,000	1,600	14,400	—	16,000
Stock-based compensation expense	—	—	—	171,249	—	171,249
Net loss	—	—	—	—	(3,874,730)	(3,874,730)
Balance, December 31, 2018	$ —	17,798,791	$ 17,799	$ 68,292,972	$ (44,132,568)	$ 24,178,203

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED DECEMBER 31, 2018 AND 2017
(Unaudited)

	2018	2017
Cash Flows From Operating Activities:		
Net loss	$ (3,874,730)	$ (3,246,166)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	171,249	290,021
Issuance of common stock for release agreement	—	257,400
Depreciation	235	642
Changes in operating assets and liabilities:		
Other receivables	818,343	—
Prepaid expenses	11,109	109,429
Accounts payable	509,988	(41,271)
Accrued expenses	18,773	55,295
Accrued compensation	182,500	140,376
Accrued interest - related parties	4,003	3,192
Due to related party	—	(10,000)
Net Cash Used In Operating Activities	(2,158,530)	(2,441,082)
Cash Flows From Financing Activities:		
Proceeds from common stock warrant exercises	16,000	1,125,148
Net proceeds from registered direct offering	—	5,482,523
Net Cash Provided By Financing Activities	16,000	6,607,671
Net Change in Cash and Cash Equivalents	(2,142,530)	4,166,589
Cash and Cash Equivalents - Beginning of Period	9,184,003	3,204,108
Cash and Cash Equivalents - End of Period	$ 7,041,473	$ 7,370,697
Supplemental Disclosures Of Cash Flow Information and Non-cash Transactions:		
Interest paid	$ —	$ 192
Par value of common stock issued upon cashless exercise of warrants	$ —	$ 17

See notes to unaudited condensed consolidated financial statements.

CITIUS PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED DECEMBER 31, 2018 AND 2017
(Unaudited)

1. NATURE OF OPERATIONS, BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business

Citius Pharmaceuticals, Inc. ("Citius" or the "Company") is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on anti-infectives, cancer care and unique prescription products.

On March 30, 2016, Citius acquired Leonard-Meron Biosciences, Inc. ("LMB") as a wholly-owned subsidiary. The Company acquired all of the outstanding stock of LMB by issuing shares of its common stock. The net assets acquired, included identifiable intangible assets of $19,400,000 related to in-process research and development. The Company recorded goodwill of $1,586,796 for the excess of the purchase price over the net assets.

In-process research and development represents the value of LMB's leading drug candidate which is an antibiotic solution used to treat catheter-related bloodstream infections (Mino-Lok®) and is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation. Goodwill represents the value of LMB's industry relationships and its assembled workforce. Goodwill will not be amortized but will be tested at least annually for impairment.

Citius is subject to a number of risks common to companies in the pharmaceutical industry including, but not limited to, risks related to the development by Citius or its competitors of research and development stage product candidates, market acceptance of its product candidates that might be approved, competition from larger companies, dependence on key personnel, dependence on key suppliers and strategic partners, the Company's ability to obtain additional financing and the Company's compliance with governmental and other regulations.

Basis of Presentation and Summary of Significant Accounting Policies

Basis of Preparation — The accompanying condensed consolidated financial statements include the operations of Citius Pharmaceuticals, Inc., and its wholly-owned subsidiaries, Citius Pharmaceuticals, LLC, and LMB. All significant inter-company balances and transactions have been eliminated in consolidation.

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information, without being audited, pursuant to the rules and regulations of the Securities and Exchange Commission. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments considered necessary to make the financial statements not misleading have been included. Operating results for the three months ended December 31, 2018 are not necessarily indicative of the results that may be expected for the year ending September 30, 2019. The unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended September 30, 2018 filed with the Securities and Exchange Commission.

There have been no recently issued accounting pronouncements that have had or are expected to have a material impact on the Company's consolidated financial statements.

Use of Estimates — Our accounting principles require our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of assets and liabilities at the date of the financial statements, and reported amounts of revenues and expenses during the reporting period. Estimates having relatively higher significance include stock-based compensation, valuation of warrants, and income taxes. Actual results could differ from those estimates and changes in estimates may occur.

Basic and Diluted Net Loss per Common Share — Basic and diluted net loss per common share is computed by dividing net loss in each period by the weighted average number of shares of common stock outstanding during such period. For the periods presented, common stock equivalents, consisting of stock options and warrants were not included in the calculation of the diluted loss per share because they were anti-dilutive.

Income Taxes — We recognize deferred tax assets and liabilities for the expected future tax consequences or events that have been included in our condensed consolidated financial statements and/or tax returns. Deferred tax assets and liabilities are based upon the differences between the financial statement carrying amounts and the tax bases of existing assets and liabilities and for loss and credit carryforwards using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We provide reserves for potential payments of tax to various tax authorities related to uncertain tax positions when management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable.

2. GOING CONCERN UNCERTAINTY AND MANAGEMENT'S PLAN

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company experienced negative cash flows from operations of $2,158,530 for the three months ended December 31, 2018. The Company has generated no operating revenue to date and has principally raised capital through the issuance of debt and equity instruments to finance its operations. At December 31, 2018, the Company had limited capital to fund its operations. This raises substantial doubt about the Company's ability to continue as a going concern.

The Company plans to raise capital through equity financings from outside investors as well as raise additional funds from existing investors and continued borrowings under related party debt agreements. There is no assurance, however, that the Company will be successful in raising the needed capital and, if funding is available, that it will be available in amounts sufficient for and on terms acceptable to the Company. The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of the above uncertainty.

3. PATENT AND TECHNOLOGY LICENSE AGREEMENTS

LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT") to develop and commercialize Mino-Lok® on an exclusive, worldwide sub licensable basis, as amended. LMB pays an annual maintenance fee in June until commercial sales of a product subject to the license commence.. There was no maintenance fee paid in each of the three month periods ended December 31, 2018 and 2017.

LMB will also pay annual royalties on net sales of licensed products, with royalties ranging from the mid-single digits to the low double digits. In limited circumstances in which the licensed product is not subject to a valid patent claim and a competitor is selling a competing product, the royalty rate is in the low single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties of $100,000 in the first commercial year which is prorated for a less than 12-month period, increasing $25,000 per year to a maximum of $150,000 annually. LMB must also pay NAT up to $1,390,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub licensees.

Unless earlier terminated by NAT, based on the failure to achieve certain development and commercial milestones, the license agreement remains in effect until the date that all patents licensed under the agreement have expired and all patent applications within the licensed patent rights have been cancelled, withdrawn or expressly abandoned.

See Note 8 for a description of the patent and technology license agreement that we entered into with the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center on January 2, 2019.

4. NOTES PAYABLE – RELATED PARTIES

The aggregate principal balance as of December 31, 2018 consists of notes payable held by our Chairman, Leonard Mazur, in the amount of $160,470 and notes payable held by our Chief Executive Officer, Myron Holubiak, in the amount of $12,500. Notes with an aggregate principal balance of $104,000 accrue interest at the prime rate plus 1.0% per annum and notes with an aggregate principal balance of $68,970 accrue interest at 12% per annum.

Interest expense on notes payable – related parties was $4,003 and $3,192, respectively, for the three months ended December 31, 2018 and 2017.

5. COMMON STOCK, STOCK OPTIONS AND WARRANTS

2017 Public Offering and Release Agreement

On November 7, 2017, the Company entered into a release agreement with the underwriter of the public offering closed in August 2017. The Company had previously granted a right of first refusal to underwrite all equity and debt offerings for a period of twelve months following completion of the August 2017 public offering ("Right of First Refusal"). Under the release, the Company agreed to pay the underwriter $100,000 in cash and issue 60,000 shares of restricted common stock with a fair value of $257,400 in exchange for a full release from all obligations related to the Right of First Refusal. The Company expensed the $357,400 cost of the release agreement in November 2017.

Registered Direct/Private Placement Offerings

On December 19, 2017, the Company closed a registered direct offering with several institutional and accredited investors for the sale of 1,280,360 shares of common stock at $4.6925 per share for gross proceeds of $6,008,089. Simultaneously, the Company privately sold and issued to the investors 640,180 immediately exercisable five and a half year warrants with an exercise price of $4.63 per share. The Company paid the placement agent for the offering a fee of 7% of the gross proceeds totaling $420,566 and issued the placement agent 89,625 immediately exercisable five-year warrants with an exercise price of $5.8656 per share. The Company also reimbursed the placement agent for $85,000 in expenses and incurred $20,000 in other expenses. Net proceeds from the offering were $5,482,523. The estimated fair value of the 640,180 warrants issued to the investors was $2,407,276 and the estimated fair value of the 89,625 warrants issued to the placement agent was $316,071.

On March 29, 2018, the Company closed a registered direct offering with an institutional and an accredited investor for the sale of 669,504 shares of common stock at $2.985 per share for gross proceeds of $1,998,469. Simultaneously, the Company privately sold and issued to investors 669,504 immediately exercisable five and a half year warrants with an exercise price of $2.86 per share. The Company paid the placement agent for the offering a fee of 7% of the gross proceeds totaling $139,893 and issued the placement agent 46,866 immediately exercisable five-year warrants with an exercise price of $3.73125 per share. The Company also reimbursed the placement agent for $85,000 in expenses and incurred $10,000 in other expenses. Net proceeds from the offering were $1,763,576. The estimated fair value of the 669,504 warrants issued to the investors was $1,679,482 and the estimated fair value of the 46,866 warrants issued to the placement agent was $110,511.

August 2018 Offering

On August 13, 2018, Citius closed an underwritten offering of (i) 5,521,569 units, each unit consisting of one share of common stock and one immediately exercisable five-year warrant to purchase one share with an exercise price of $1.15 per share, and (ii) 2,321,569 pre-funded units, each pre-funded unit consists of one pre-funded warrant to purchase one share and one immediately exercisable five-year warrant to purchase one share with an exercise price of $1.15 per share. The pre-funded warrants included in the pre-funded units are immediately exercisable at a price of $0.01 per share and do not expire. The offering price was $1.275 per unit and $1.265 per pre-funded unit. The net proceeds of the offering were $8,926,786. The Company issued underwriter warrants to purchase up to 549,020 shares with an exercise price of $1.59375 per share with an estimated fair value of $491,737. The underwriter warrants are exercisable following February 8, 2019 and expire on August 8, 2023. The estimated fair value of the 2,321,569 pre-funded warrants was $2,630,072, and the estimated fair value of the 7,843,138 warrants included in the units and the pre-funded units issued to the investors was $7,311,727.

Unit Purchase Options

On April 7, 2017, the Company issued a three-year Unit Purchase Option Agreement for 38,000 units at a purchase price of $9.00 per unit. Each unit consists of one share of common stock and a warrant to purchase one share of common stock at an exercise price of $9.00 per share which expires on the earlier of three years after exercise of the Unit Purchase Option Agreement or April 7, 2023.

On June 29, 2017, the Company issued a three-year Unit Purchase Option Agreement for 62,667 units at a purchase price of $9.00 per unit. Each unit consists of one share of common stock and a warrant to purchase one share of common stock at an exercise price of $9.00 per share which expires on the earlier of three years after exercise of the Unit Purchase Option Agreement or June 29, 2022. The Company estimated the fair value of the unit purchase option agreement at $193,860 and recorded it as a prepaid expense. The Company recorded an expense of $96,930 for this agreement during the year ended September 30, 2017 and expensed the remaining balance of $96,930 during the three months ended December 31, 2017.

Common Stock Issued for Services

On February 7, 2018, the Company issued 22,200 shares of common stock for services provided by two consultants and expensed the $88,800 fair value of the common stock issued. On April 1, 2018, the Company issued 10,000 shares of common stock for services provided by a consultant and expensed the $31,000 fair value of the common stock issued.

Stock Option Plans

Pursuant to its 2014 Stock Incentive Plan (the "2014 Plan") the Company has reserved 866,667 shares of common stock for issuance to employees, directors and consultants. The Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards and cash-based awards under the 2014 Plan. As of December 31, 2018, there were options to purchase an aggregate of 856,039 shares of common stock outstanding under the 2014 Plan, options to purchase 4,829 shares were exercised, and 5,799 shares remain available for future grants.

On February 7, 2018, our stockholders approved the 2018 Omnibus Stock Incentive Plan (the "2018 Plan") and the Company reserved 2,000,000 shares of common stock for issuance to employees, directors and consultants. Pursuant to the 2018 Plan, the Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant stock options, stock appreciation rights, restricted stock, restricted stock units, other stock-based awards and cash-based awards. As of December 31, 2018, there were options to purchase an aggregate of 745,000 shares of common stock outstanding under the 2018 Plan and 1,255,000 shares available for future grants.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. Due to its limited operating history and limited number of sales of its common stock, the Company estimated its volatility in consideration of a number of factors including the volatility of comparable public companies. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The expected term of stock options granted, all of which qualify as "plain vanilla," is based on the average of the contractual term (generally 10 years) and the vesting period. For non-employee options, the expected term is the contractual term.

A summary of option activity under the 2014 Plan and 2018 Plan is presented below:

	Option Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at October 1, 2018	1,601,039	$ 4.35	8.56 years	$ 173,291
Granted	—	—		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding at December 31, 2018	1,601,039	$ 4.35	8.31 years	$ 68,056
Exercisable at December 31, 2018	752,809	$ 7.07	6.90 years	$ 68,056

Stock-based compensation expense for the three months ended December 31, 2018 and 2017 was $171,249 and $290,021, respectively.

At December 31, 2018, unrecognized total compensation cost related to unvested awards of $1,158,589 is expected to be recognized over a weighted average period of 2.13 years.

Warrants

As of December 31, 2018, the Company has reserved shares of common stock for the exercise of outstanding warrants. The following table summarizes the warrants outstanding:

	Exercise price	Number	Expiration Dates
Investor and Placement Agent Warrants	$ 9.00	384,006	September 12, 2019
Investor Warrants	9.00	202,469	March 19, 2020 – September 14, 2020
Investor Warrants	9.00	307,778	November 5, 2020 – April 25, 2021
LMB Warrants	6.15	90,151	June 12, 2019 – March 2, 2021
LMB Warrants	9.90	8,155	September 30, 2019 – January 8, 2020
LMB Warrants	20.70	17,721	November 3, 2019 – March 6, 2020
LMB Warrants	7.50	73,883	August 18, 2020 – March 14, 2021
LMB Warrants	7.50	53,110	March 24, 2022 – April 29, 2022
Financial Advisor Warrants	3.00	25,833	August 15, 2021
2016 Offering Warrants	4.13	140,819	November 23, 2021 – February 27, 2022
Convertible Note Warrants	9.75	40,436	September 12, 2019
2017 Public Offering Warrants	4.13	1,622,989	August 2, 2022
2017 Public Offering Underwriter Warrants	4.54	65,940	February 2, 2023
December 2017 Registered Direct/Private Placement Offering Investor Warrants	4.63	640,180	June 19, 2023
December 2017 Registered Direct/Private Placement Offering Placement Agent Warrants	5.87	89,625	December 19, 2022
March 2018 Registered Direct/Private Placement Offering Investor Warrants	2.86	669,504	October 2, 2023
March 2018 Registered Direct/Private Placement Offering Placement Agent Warrants	3.73	46,866	March 28, 2023
August 2018 Offering Investor Warrants	1.15	7,843,138	August 14, 2023
August 2018 Offering Pre-Funded Unit Warrants	0.01	721,569	No expiration date
August 2018 Offering Agent Warrants	1.59	549,020	August 8, 2023
		13,593,192	

During the three months ended December 31, 2017, 40,834 of the Financial Advisor Warrants were exercised on a cashless basis resulting in the issuance of 16,547 shares of common stock and 272,767 of warrants issued in the August 2017 public offering were exercised at $4.125 per share for net proceeds of $1,125,148.

During the three months ended December 31, 2018, 1,600,000 of the August 2018 Offering Pre-Funded Unit Warrants were exercised at $0.01 per share for net proceeds of $16,000.

At December 31, 2018, the weighted average remaining life of the outstanding warrants is 3.98 years, all warrants are exercisable, and the aggregate intrinsic value for the warrants outstanding was $743,216.

Common Stock Reserved

A summary of common stock reserved for future issuances as of December 31, 2018 is as follows:

Stock plan options outstanding	1,601,039
Stock plan shares available for future grants	1,260,799
Warrants outstanding	13,593,192
Unit purchase options outstanding	201,334
Total	16,656,364

6. RELATED PARTY TRANSACTIONS

Our Chairman of the Board, Leonard Mazur, is the cofounder and Vice Chairman of Akrimax Pharmaceuticals, LLC ("Akrimax"), a privately held pharmaceutical company specializing in producing cardiovascular and general pharmaceutical products. The Company leases office space from Akrimax (see Note 7).

The Company has outstanding debt due to Leonard Mazur (Chairman of the Board) and Myron Holubiak (Chief Executive Officer) (see Note 4).

In connection with the December 2017 Registered Direct/Private Placement Offering, Mr. Mazur purchased 213,106 shares of common stock at $4.6925 per share and received 106,553 warrants with an exercise price of $4.63 per share (See Note 5). In connection with the March 2018 Registered Direct/Private Placement Offering, Mr. Mazur purchased 167,504 shares of common stock at $2.985 per share and received 167,504 warrants with an exercise price of $2.86 per share (See Note 5). The purchases were made on the same terms as for all other investors.

In connection with the August 2018 offering, Mr. Mazur purchased 3,137,255 shares of common stock at $1.275 per share and received 3,137,255 warrants with an exercise price of $1.15 per share, and Mr. Holubiak purchased 784,314 shares of common stock at $1.275 per share and received 784,314 warrants with an exercise price of $1.15 per share (See Note 5). The purchases were made on the same terms as for all other investors.

General and administrative expense for the three months ended December 31, 2018 and 2017 includes $12,000 for both periods paid to a financial consultant who is a stockholder of the Company.

7. OPERATING LEASE

LMB leases office space from Akrimax (see Note 6) in Cranford, New Jersey at a monthly rental rate of $2,167 pursuant to an agreement which currently expires on April 30, 2019. Rent expense for the three months ended December 31, 2018 and 2017 was $6,501 for both periods.

8. SUBSEQUENT EVENTS

Patent and Technology License Agreement – Mino-Wrap

On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center ("Licensor"), whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants. We intend to develop, a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries, ("Mino-Wrap"). We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the U.S. Food and Drug Administration.

Under the license agreement, the Company paid a nonrefundable upfront payment of $125,000 recorded as research and development expense. We are obligated to pay an annual maintenance fee of $30,000, commencing in January 2020 that increases annually by $15,000 per year up to a maximum of $90,000. Annual maintenance fees cease on the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of $100,000 that will increase annually by $25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution and maintenance of all patents. The agreement expires on the later of the expiration of the patents or January 2, 2034.

Exercise of Pre-Funded Unit Warrants

On January 14, 2019, the Company received a notice of exercise for the purchase of the remaining 721,569 shares of common stock at $0.01 per share pursuant to its pre-funded unit warrants issued in the August 2018 offering. Proceeds from the exercise were $7,216.

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

The following discussion and analysis of our financial condition and results of operations for the three months ended December 31, 2018 should be read together with our unaudited consolidated financial statements and related notes included elsewhere in this report and in conjunction with the audited financial statements of Citius Pharmaceuticals, Inc. included in our Annual Report on Form 10-K for the year ended September 30, 2018. The following discussion contains "forward-looking statements" that reflect our future plans, estimates, beliefs and expected performance. Our actual results may differ materially from those currently anticipated and expressed in such forward-looking statements as a result of a number of factors. We caution that assumptions, expectations, projections, intentions or beliefs about future events may, and often do, vary from actual results and the differences can be material. Please see "Cautionary Note Regarding Forward-Looking Statements."

Historical Background

Citius Pharmaceuticals, Inc. ("Citius" or the "Company") is a specialty pharmaceutical company dedicated to the development and commercialization of critical care products targeting unmet needs with a focus on anti-infectives, cancer care and unique prescription products. On September 12, 2014, we acquired Citius Pharmaceuticals, LLC as a wholly-owned subsidiary.

On March 30, 2016, the Company acquired all of the outstanding stock of Leonard-Meron Biosciences, Inc. ("LMB") by issuing 1,942,956 shares of its common stock. As of March 30, 2016, the stockholders of LMB received approximately 41% of the issued and outstanding common stock of the Company. In addition, the Company converted the outstanding common stock warrants of LMB into 243,020 common stock warrants of the Company and converted the outstanding common stock options of LMB into 77,252 common stock options of the Company. Management estimated the fair value of the purchase consideration to be $19,015,073.

In connection with the acquisition, the Company acquired net assets of $17,428,277, including identifiable intangible assets of $19,400,000 related to in-process research and development. The Company recorded goodwill of $1,586,796 for the excess of the purchase price over the net assets acquired.

In-process research and development represents the value of LMB's leading drug candidate, Mino-Lok®, which is an antibiotic solution used to treat catheter-related bloodstream infections. Goodwill represents the value of LMB's industry relationships and its assembled workforce. In-process research and development is expected to be amortized on a straight-line basis over a period of eight years commencing upon revenue generation. Goodwill will not be amortized, but will be tested at least annually for impairment.

Through December 31, 2018, the Company has devoted substantially all of its efforts to product development, raising capital, building infrastructure through strategic alliances and coordinating activities relating to its proprietary products. On July 1, 2016, the Company announced that it was discontinuing Suprenza, its first commercial product, for strategic reasons and not due to safety or regulatory concerns, and was focusing on the Phase 3 development of Mino-Lok®, and the Phase 2b development of Hydro-Lido for hemorrhoids. The Company has not yet realized any revenues from its planned principal operations.

Patent and Technology License Agreements

Mino-Lok® - LMB has a patent and technology license agreement with Novel Anti-Infective Therapeutics, Inc. ("NAT") to develop and commercialize Mino-Lok® on an exclusive, worldwide sub-licensable basis, as amended. Since May 2014, LMB has paid an annual maintenance fee, which began at $30,000 and that increases over five years to $90,000, where it is to remain until commercial sales of a product subject to the license commence. LMB will also pay annual royalties on net sales of licensed products, with royalties ranging from the mid-single digits to the low double digits. In limited circumstances in which the licensed product is not subject to a valid patent claim and a competitor is selling a competing product, the royalty rate is in the low single digits. After a commercial sale is obtained, LMB must pay minimum aggregate annual royalties that increase in subsequent years. LMB must also pay NAT up to $1,390,000 upon achieving specified regulatory and sales milestones. Finally, LMB must pay NAT a specified percentage of payments received from any sub licensees.

Mino-Wrap - On January 2, 2019, we entered into a patent and technology license agreement with the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center ("Licensor"), whereby we in-licensed exclusive worldwide rights to the patented technology for any and all uses relating to breast implants. We intend to develop, a liquefying gel-based wrap containing minocycline and rifampin for the reduction of infections associated with breast implants following breast reconstructive surgeries, ("Mino-Wrap"). We are required to use commercially reasonable efforts to commercialize Mino-Wrap under several regulatory scenarios and achieve milestones associated with these regulatory options leading to an approval from the U.S. Food and Drug Administration.

Under the license agreement, the Company paid a nonrefundable upfront payment of $125,000. We are obligated to pay an annual maintenance fee of $30,000, commencing in January 2020, that increases annually by $15,000 per year up to a maximum of $90,000. Annual maintenance fees cease on the first sale of product. We also must pay up to an aggregate of $2.1 million in milestone payments, contingent on the achievement of various regulatory and commercial milestones. Under the terms of the license agreement, we also must pay a royalty of mid- to upper-single digit percentages of net sales, depending on the amount of annual sales, and subject to downward adjustment to lower- to mid-single digit percentages in the event there is no valid patent for the product in the United States at the time of sale. After the first sale of product, we will owe an annual minimum royalty payment of $100,000 that will increase annually by $25,000 for the duration of the term. We will be responsible for all patent expenses incurred by Licensor for the term of the agreement although Licensor is responsible for filing, prosecution and maintenance of all patents. The agreement expires on the later of the expiration of the patents or January 2, 2034.

RESULTS OF OPERATIONS

Three months ended December 31, 2018 compared with the three months ended December 31, 2017

	Three Months Ended December 31, 2018	Three Months Ended December 31, 2017
Revenues	$ —	$ —
Operating expenses:		
Research and development	2,113,101	606,521
General and administrative	1,588,124	2,346,240
Stock-based compensation expense	171,249	290,021
Total operating expenses	3,872,474	3,242,782
Operating loss	(3,872,474)	(3,242,782)
Interest income	1,747	—
Interest expense	(4,003)	(3,384)
Net loss	$ (3,874,730)	$ (3,246,166)

Revenues

We did not generate any revenues for the three months ended December 31, 2018 and 2017.

Research and Development Expenses

For the three months ended December 31, 2018, research and development expenses were $2,113,101 as compared to $606,521 during the three months ended December 31, 2017. The $1,506,580 increase in 2018 was primarily due to the ongoing Phase 3 trial of Mino-Lok® which commenced during the quarter ended March 31, 2018. Research and development costs for Mino-Lok® were $1,994,103 for the three months ended December 31, 2018 as compared to $561,183 for the three months ended December 31, 2017. Research and development costs for our Hydro-Lido product candidate were $118,998 for the three months ended December 31, 2018 as compared to $45,338 for the three months ended December 31, 2017. We expect that research and development expenses will increase in fiscal 2019 as we continue to focus on our Phase 3 trial for Mino-Lok® and commence our research and development efforts related to the recently acquired Mino-Wrap license agreement. We are actively seeking to raise additional capital in order to fund our research and development efforts.

General and Administrative Expenses

For the three months ended December 31, 2018, general and administrative expenses were $1,588,124 as compared to $2,346,240 during the three months ended December 31, 2017. General and administrative expenses decreased by $758,116 in comparison with the prior period. The decrease was primarily due to $357,400 in settlement costs incurred in the prior period for the termination of the right of first refusal agreement with the underwriter of our 2017 public offering and a decrease of $574,844 in investor relations expenses. General and administrative expenses consist primarily of compensation costs, consulting fees incurred for financing activities and corporate development services, and investor relations expenses.

Stock-based Compensation Expense

For the three months ended December 31, 2018, stock-based compensation expense was $171,249 as compared to $290,021 for the three months ended December 31, 2017. Stock-based compensation expense includes the expense for options assumed in the March 30, 2016 acquisition of LMB, as well as grants to directors, employees and consultants. Stock-based compensation expense for the current quarter decreased by $118,772 as certain options, including all of the options assumed in the acquisition of LMB, have been fully expensed.

Other Income (Expense)

Interest income for the three months ended December 31, 2018 was $1,747 as we invested some of the proceeds from the August 2018 offering. There was no interest income for the three months ended December 31, 2017.

Interest expense for the three months ended December 31, 2018 was $4,003 compared to $3,384 for the three months ended December 31, 2017. Interest expense on the notes payables acquired in the acquisition of LMB increased due to the increase in the prime rate.

Net Loss

For the three months ended December 31, 2018, we incurred a net loss of $3,874,730 compared to a net loss for the three months ended December 31, 2017 of $3,246,166. The $628,564 increase in the net loss was due to the increase of $1,506,580 in research and development expenses being offset by the $758,116 decrease in general and administrative expenses and the $118,772 decrease in stock-based compensation expense.

LIQUIDITY AND CAPITAL RESOURCES

Going Concern Uncertainty and Working Capital

Citius has incurred operating losses since inception and incurred a net loss of $3,874,730 for the three months ended December 31, 2018. At December 31, 2018, Citius had an accumulated deficit of $44,132,568. Citius' net cash used in operations during the three months ended December 31, 2018 was $2,158,530.

Our September 30, 2018 consolidated financial statements contain an emphasis of a matter regarding managements determination that there is substantial doubt about our ability to continue as a going concern and that the consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern.

As of December 31, 2018, Citius had working capital of $3,187,992. Our limited working capital is attributable to the operating losses incurred by the Company since inception offset by our capital raising activities. At December 31, 2018, Citius had cash and cash equivalents of $7,041,473 available to fund its operations. The Company's primary sources of cash flow since inception have been from financing activities. During the three months ended December 31, 2018, the Company received net proceeds of $16,000 from the exercise of warrants. Our primary uses of operating cash were for product development and commercialization activities, employee compensation, consulting fees, legal and accounting fees, insurance and investor relations expenses.

We expect that we will have sufficient funds to continue our operations through June 2019. We plan to raise additional capital in the future to support our operations. There is no assurance, however, that we will be successful in raising the needed capital or that the proceeds will be received in a timely manner to fully support our operations.

Inflation

Our management believes that inflation has not had a material effect on our results of operations.

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements.

Critical Accounting Policies and Estimates

The preparation of our financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities as of the date of the financial statements and the amounts of revenues and expenses recorded during the reporting periods. We base our estimates on historical experience, where applicable and other assumptions that we believe are reasonable under the circumstances. Actual results may differ from our estimates under different assumptions or conditions.

Our critical accounting policies and use of estimates are discussed in, and should be read in conjunction with, the annual consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended September 30, 2018 as filed with the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosure.

Our Chief Executive Officer (who is our principal executive officer) and Chief Financial Officer (who is our principal financial officer and principal accounting officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act) as of December 31, 2018. In designing and evaluating disclosure controls and procedures, we recognize that any disclosure controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objective. As of December 31, 2018, based on the evaluation of these disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes In Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

There has been no change in the Company's risk factors since the Company's Form 10-K filed with the SEC on December 11, 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	Patent and Technology License Agreement, dated January 2, 2019, between the Board of Regents of the University of Texas System on behalf of the University of Texas M. D. Anderson Cancer Center and Citius Pharmaceuticals, Inc.* +
10.2	First Amendment, dated October 15, 2015, to Patent and Technology License Agreement, dated May 14, 2014, between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc.
10.3	Patent and Technology License Agreement, dated May 14, 2014, between Novel Anti-Infective Technologies, LLC and Leonard-Meron Biosciences, Inc. *+
31.1	Certification of the Principal Executive Officer pursuant to Exchange Act Rule 13a-14(a).*
31.2	Certification of the Principal Financial Officer pursuant to Exchange Act Rule 13a-14(a).*
32.1	Certification of the Principal Executive and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.*
EX-101.INS	XBRL INSTANCE DOCUMENT*
EX-101.SCH	XBRL TAXONOMY EXTENSION SCHEMA DOCUMENT*
EX-101.CAL	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE*
EX-101.DEF	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE*
EX-101.LAB	XBRL TAXONOMY EXTENSION LABELS LINKBASE*
EX-101.PRE	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE*

* Filed herewith.

+ Confidential treatment has been requested with respect to certain portions of this exhibit. The omitted portions have been filed separately with the SEC.

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.

CITIUS PHARMACEUTICALS, INC.

Date: February 14, 2019

By: /s/ *Myron Holubiak*
Myron Holubiak
Chief Executive Officer
(Principal Executive Officer)

Date: February 14, 2019

By: /s/ *Jaime Bartushak*
Jaime Bartushak
Chief Financial Officer
(Principal Financial and Accounting Officer)

***Portions of this exhibit marked [*] are requested to be treated confidentially.**

Patent and Technology License Agreement

This Patent and Technology License Agreement ("**Agreement**") is made by and between The Board of Regents ("**Board**") of The University of Texas System ("**System**"), an agency of the State of Texas, whose address is 210 West 7th Street, Austin, Texas 78701, on behalf of The University of Texas M. D. Anderson Cancer Center ("**MD Anderson**"), a member institution of System, and Citius Pharmaceuticals, Inc., a Nevada corporation having a principal place of business located at 11 Commerce Drive, First Floor, Cranford, New Jersey 07016 ("**Licensee**").

Recitals

A. Board owns Licensed Subject Matter (defined below).

B. Board, through MD Anderson, has determined that development and commercialization of the Licensed Subject Matter is in the public's best interest and is consistent with Board's educational and research missions and goals.

C. Board desires to have the Licensed Subject Matter developed and commercialized for the benefit of Licensee, the inventors, Board, System, MD Anderson, and the public.

D. Licensee desires to secure a license to practice the Licensed Subject Matter.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the parties agree as follows:

I. Effective Date

1.1 This Agreement is effective as of the date fully executed by all parties ("**Effective Date**").

II. Definitions

As used in this Agreement, the following terms have the meanings indicated:

2.1 **Affiliate** means any business entity which, before or after the Effective Date, directly or indirectly through one (1) or more intermediaries controls, is controlled by or is under common control with Licensee. For purposes of this definition, a business entity shall be deemed to "control" another business entity if it (a) owns, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of such other business entity, or has other comparable ownership interest with respect to any business entity other than a corporation, or (b) has the power, whether pursuant to contract, ownership of securities or otherwise, to direct the management and policies of the business entity.

2.2 **Combination Product** means any product comprised of a combination of (i) a Licensed Product and (ii) any active ingredient(s), device(s), delivery system(s) or other technology(ies) for which rights are not included in the license granted under this Agreement but, with respect to the item(s) in (ii), which may each or collectively form the basis for a separately saleable product (an **"Independent Subproduct"**).

2.3 **Control** including the correlative terms "Controls," "Controlled by," and "under common Control with," means (a) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies (whether through ownership of securities or any partnership or other ownership interest, by contract or otherwise) of a Person, or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the outstanding securities or other ownership interest of such Person.

2.4 **Change of Control** means any of the following, pursuant to any transaction or series of related transactions occurring on or after the Effective Date:

(a) any person, corporation, partnership, syndicate, trust, estate or other Group (as defined in Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act")), acting with a view to the acquisition, holding or disposition of securities or ownership interests of Licensee, (i) becomes, directly or indirectly through one or more series of transactions, the beneficial owner, as defined in Rule 13d-3 under the Exchange Act ("Beneficial Owner"), of securities or other ownership interests of Licensee representing more than fifty percent (50%) of the voting power of all outstanding securities or other ownership interests of Licensee having the right under ordinary circumstances to vote at an election of the Board of Directors or other governing body of such Licensee (the "Licensee Voting Securities"), or (ii) becomes in direct or indirect Control of the Licensee; provided, however, that the sale by Licensee of shares of its capital stock to investors in bona fide equity financing transactions are not a Change of Control for purposes of this Section 2.4(a), but only to the extent that existing stockholders of Licensee owning, in the aggregate, ninety-five percent (95.0%) of the issued and outstanding securities of the Licensee do not receive any proceeds from, related to, or otherwise in connection with such bona fide equity financing transactions;

(b) the consummation of a reorganization, merger, consolidation, or similar transaction involving Licensee, unless,

(i) the stockholders or other equity owners of Licensee immediately prior to the reorganization, merger, consolidation, or similar transaction involving Licensee, beneficially own, in the aggregate, immediately after the reorganization, merger, consolidation, or similar transaction, shares or other ownership interests entitling such stockholders to beneficially own, in the aggregate, fifty percent (50.0%) or more of the voting power of the outstanding securities or other ownership interests of the corporation or entity resulting from or surviving such reorganization, merger, consolidation, or similar transaction, or having the right under ordinary circumstances to vote at an election of the board of directors or other governing body of such resulting corporation or entity in substantially the same proportions as their ownership, immediately prior to such reorganization, merger, consolidation, or similar transaction, of the Licensee Voting Securities; or

(ii) the individuals serving as members of the Board of Directors or other governing body of Licensee, immediately prior to the reorganization, merger, consolidation, or similar transaction, constitute, immediately after such reorganization, merger, consolidation, or similar transaction, all of the board of directors or other governing body of the corporation or other entity surviving or resulting from such reorganization, merger, consolidation, or similar transaction;

(c) the consummation of a sale or other disposition of all or a material portion of the assets of Licensee or one of Licensee's Affiliates, in either case including the Licensed Subject Matter, and including without limitation, an assignment of this Agreement to a party other than an Affiliate of Licensee ("Assignment");

(d) an initial public offering by the Licensee or by one of the Licensee's Affiliates provided that such Affiliate is a sublicensee under this Agreement or has been extended rights by Licensee under this Agreement; or

(e) the approval of the stockholders or other equity owners of Licensee or one of Licensee's Affiliates of a plan of complete liquidation of the Licensee or such Licensee Affiliate; provided, however, that a liquidation in which none of the common and the preferred stockholders or other equity owners of the Licensee or Licensee's Affiliates, as applicable, has received any distribution as a result of the liquidation preference of Licensee is not a Change of Control for purposes of this Section 2.4(d).

2.5 **European Union** means the countries comprising the European Union as of the Effective Date.

2.6 **Independent Subproduct** shall have the meaning set forth in Section 2.2.

2.7 **Licensed Field** means any and all uses and applications relating to breast implants, including without limitation coatings and expanders used for either reconstructive or cosmetic purposes. The Licensed Field excludes any use or application other than with respect to breast implants.

2.8 **Licensed Products** means any material, composition, product, or service comprising, using, or made using any portion of Licensed Subject Matter.

2.9 **Licensed Subject Matter** means (a) Patent Rights, (b) Technology Rights, and/or (c) inventions covered by Patent Rights and/or Technology Rights.

2.10 **Licensed Territory** means worldwide.

2.11 **Net Sales** means the gross revenues invoiced by, or on behalf of Licensee or its Affiliate(s) from a Sale less the following items, to the extent that such items have not been previously accounted for in the invoiced amount:

(a) trade, quantity, and other discounts actually granted;
(b) rebates, credits, and chargeback payments actually granted to managed health care organizations, wholesalers, or to federal, state/provincial, local and other governments, including their agencies, purchasers, and/or reimbursers;
(c) sales and/or use taxes actually paid;
(d) import or export duties, tariffs, or taxes actually paid;
(e) transportation and insurance charges actually paid or allowed;
(f) allowances, rebates, credits, or refunds for returned or defective goods (not exceeding the original billing or invoice amount);

all as recorded by Licensee in its official books and records in accordance with applicable generally accepted accounting practices and consistent with their financial statements and/or, if applicable, regulatory filings with the United States Securities and Exchange Commission.

If a Licensed Product is sold as part of a Combination Product, Net Sales shall be calculated by multiplying Net Sales for such Combination Product by the fraction A/(A+B) ("Reduction Factor") where A is the invoice price of the Licensed Product when sold separately, and B is the aggregate invoice price of the Independent Subproduct(s) in the combination when sold separately. If either the Licensed Product or the Independent Subproduct(s) is(are) not at that time sold separately, then the allocation of Net Sales shall be commercially reasonable and determined by good faith negotiation between MD Anderson and Licensee, based on the relative value of the Licensed Product and Independent Subproduct(s), consistent with the formula provided above but, in such case, Licensee shall have no right to sell the combination product until MD Anderson and Licensee have reached a written agreement with respect to the royalty rate to be paid by Licensee with respect to such combination product. Notwithstanding the foregoing, in no event shall the Reduction Factor for Net Sales for the Combination Product in such written agreement be less than fifty percent (50%).

2.12 **Patent Expenses** means documented out-of-pocket expenses incurred by MD Anderson in preparing (including conducting prior art searches, if any), filing, prosecuting (including post-grant proceedings), defending, enforcing and maintaining patent applications and patents under Patent Rights.

2.13 **Patent Rights** means the Board's rights in:

(a) the patents and patent applications listed in Exhibit I to this Agreement;

(b) all non-provisional patent applications that claim priority to, or common priority with, any of the provisional applications listed in subpart (a) provided that the claims of such non-provisional applications are entitled to claim priority to such provisional applications;

(c) all divisionals, continuations and continuations-in-part of the non-provisional patent applications identified in (a) and (b), above provided that the claims of such continuations-in-part are entitled to claim priority to at least one of the patent applications identified in (a) or (b), above;

(d) all reissues, reexaminations, extensions, supplementary protection certificates, and foreign counterparts of any of the patents or patent applications identified in (a), (b) or (c), above; and

(e) any patents that issue with respect to any of the patent applications listed in (a), (b), (c) or (d), above.

2.14 For purposes of Section 2.3, **Person** means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, governmental authority or agency, or any form of legal entity under applicable laws not specifically listed herein.

2.15 **Regulatory Approval** means the approval or clearance needed in a particular country or jurisdiction by a Regulatory Authority to begin marketing and/or sale of a Licensed Product in such country or jurisdiction, which shall include, if applicable, pricing approvals.

2.16 **Regulatory Authority** means any applicable governmental regulatory authority involved in granting approvals for marketing and/or sale of a Licensed Product, including without limitation, the United States Food and Drug Administration ("**FDA**").

2.17 **Sale, Sell,** or **Sold** means the transfer or disposition of a Licensed Product for value by Licensee or any Affiliate of Licensee; provided, however, that the following transfers and dispositions of a Licensed Product for value shall not be included in Sales:

(a) Any transfer to a Royalty Free Practitioner. As used herein, "**Royalty-Free Practitioner**" means MD Anderson and the following individuals: Issam Raad, M.D.; George Viola, M.D.; and Jesse Selber, M.D. ("**Physician Inventors**"), and any partner or associate who practices medicine with one or more of the Physician Inventors, but with respect to such partner or associate, only for such time as he/she is engaged in a bona fide medical practice with one or more of the Physician Inventors;

(b) Any transfer to Licensee or any Affiliate of Licensee, unless such Licensee or Affiliate acquires such Licensed Product for end use; and

(c) Any transfer of Licensed Products provided for clinical trials, research purposes, or charitable or compassionate use purposes for consideration at or below cost.

2.18 **Technology Rights** means Board's rights in technical information, know-how, processes, procedures, compositions, devices, methods, formulas, protocols, techniques, designs, drawings or data created at MD Anderson before the Effective Date by the inventor(s) listed in Exhibit I while employed at MD Anderson and within the Licensed Field which (a) are not covered by Patent Rights, (b) facilitate the practice, development, manufacture, use, and/or selling of invention(s) claimed in the patents and/or patent applications listed in the definition of Patent Rights, whether outstanding, expired or abandoned; and (c) have no obligations or encumbrances in favor of or benefitting any third party and are not otherwise subject to contractual or legal restrictions that would preclude a license to Licensee under this Agreement.

2.19 **Valid Claim** means a claim of (a) an issued and unexpired patent included within the Patent Rights unless the claim has been held unenforceable or invalid by the final, un-reversed, and un-appealable decision of a court or other governmental body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or finally determined by the relevant governmental authority to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (b) a pending patent application within the Patent Rights to the extent the claim continues to be prosecuted in good faith.

III. License

3.1 Board, through MD Anderson, hereby grants to Licensee a royalty-bearing, exclusive license (with no right to grant sublicenses) under Patent Rights to manufacture, have manufactured, use, import, offer to sell and/or sell Licensed Products within Licensed Territory for use within Licensed Field.

3.2 Board, through MD Anderson, hereby grants to Licensee a royalty-bearing, non-exclusive license (with no right to grant sublicenses) under Technology Rights to manufacture, have manufactured, use, import, offer to sell and/or sell Licensed Products within Licensed Territory for use within Licensed Field.

3.3 Licensee may extend the grants of Sections 3.1 and 3.2 to any Affiliate provided that such Affiliate consents in writing to be bound by this Agreement to the same extent as Licensee; provided, however, that such Affiliate shall not further extend or sublicense the grants of Sections 3.1 and 3.2 to another Affiliate or any other third-party. For the avoidance of doubt, if Licensee extends such license grants to one of its Affiliates, as contemplated by this Section 3.3, such Affiliate shall comply, and Licensee shall also be liable for each such Affiliate's compliance, with all of the terms and conditions of this Agreement.

3.4 The grants of this Article III are further subject to 13.2 and 13.3 hereinbelow, the payment by Licensee to MD Anderson of all consideration as provided herein, and are further subject to the following rights retained by Board and MD Anderson to:

(a) Publish the general scientific findings from research related to Licensed Subject Matter, subject to the terms of Article X– Confidential Information and Publication; and

(b) Use Licensed Subject Matter for patient care at MD Anderson, non-commercial research, teaching, and other academically-related purposes; and

(c) Transfer Licensed Subject Matter to academic or research institutions for non-commercial research use.

3.5 The parties hereby acknowledge and agree that any exercise by Licensee of the license grant set forth in this Section 3.1 and/or Section 3.2 outside the scope of the Licensed Field shall be deemed a material breach of this Agreement.

3.6 Licensee, itself or through an Affiliate, shall use commercially reasonable efforts to make Licensed Products commercially available in the Licensed Field within the Licensed Territory. The efforts of Licensee's Affiliates shall be deemed efforts of Licensee for the purpose of determining Licensee's compliance with this Section 3.6. Without limiting the foregoing, Licensee shall use commercially reasonable efforts to:

(a) maintain a bona fide, funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program (all as commercially reasonable) to make Licensed Products commercially available in the Licensed Field to the public as soon as commercially practicable within the Licensed Territory, and

(b) achieve the following Diligence Milestone Events by the deadlines indicated:

Table 3.6(b)

Diligence Milestone Events	Deadlines
1. Submit a 510(k) application to the FDA	Not later than [*] months after the Effective Date
2. Receive Regulatory Approval from FDA	Not later than [*] months after the Effective Date
3. First Sale	Not later than [*] months after the Effective Date

In the event that the FDA determines that Licensed Products must be approved via any process other than the 510(k) clearance process, and Licensee subsequently files an appeal with the FDA seeking a reexamination or reclassification of the clearance or approval process necessary to Sell Licensed Products, this Section 3.6(b) is automatically amended such that each deadline set forth in Table 3.6(b) is extended by the longer of (i) [*], or (ii) for so long as such appeal is pending before the FDA, or (iii) in the event such appeal is unsuccessful, for so long as Licensee is diligently pursuing judicial review thereof.

In the event that the FDA determines that Licensed Products must be approved via the premarket approval ("PMA") process rather than via the 510(k) clearance process, this Section 3.6(b) is automatically amended such that Diligence Milestone Event 1 of Table 3.6(b) instead reads "Submit a PMA application to the FDA," and each deadline set forth in Table 3.6(b) is extended by [*].

In the event that the FDA makes a final, unappealable decision that a New Drug Application ("NDA") is required prior to Sale of any Licensed Products, Licensee's obligations to achieve the Diligence Milestones under this Section 3.6(b) are waived.

If the obligations under Sections 3.6(a) and 3.6(b) are not fulfilled, Board and/or MD Anderson may treat such failure as a breach in accordance with Section 12.3(c).

(c) Within thirty (30) calendar days following each anniversary of the Effective Date, Licensee will deliver to MD Anderson a written progress report as to Licensee's and its Affiliates' efforts and accomplishments during the preceding year in using commercially reasonable efforts to develop and/or commercialize, as applicable, the Licensed Subject Matter in the Licensed Territory and Licensee's development and/or commercialization plans, as applicable, for the upcoming year.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

IV. Consideration, Payments and Reports

4.1 In consideration of rights granted by Board to Licensee under this Agreement, Licensee agrees to pay MD Anderson each of the following:

(a) All Patent Expenses incurred by or for MD Anderson after the Effective Date for so long as this Agreement remains in effect; provided however, that if Board, System or MD Anderson licenses Patent Rights to a party other than Licensee, then Licensee shall pay a pro rata share of the Patent Expenses incurred by MD Anderson based on the number of licenses for the Patent Rights during the time each such Patent Expense is incurred. MD Anderson will invoice Licensee on a quarterly basis after the Agreement is fully executed. The invoiced amounts will be due and payable by Licensee within thirty (30) calendar days of invoice. Patent Expense payment delinquencies will be considered a payment default under Section 12.2(b); and

(b) A nonrefundable upfront license fee in the amount of $125,000.00. This fee will not reduce the amount of any other payment provided for in this Article IV, and is due and payable within thirty (30) calendar days after the Agreement has been fully executed by all parties. The obligation to timely pay the license upfront fee is not subject to any cure period; and

(c) Until and ceasing upon the first Sale, nonrefundable annual maintenance fees ("**Annual Maintenance Fees**") in the amount of $30,000.00, increasing annually by $15,000.00 until an amount of $90,000.00 until first Sale (for example, the Annual Maintenance Fees due for the second, and third, fourth, and fifth anniversaries of the Effective Date would be $45,000.00, and $60,000.00, $75,000.00, and $90,000.00, respectively, assuming such Annual Maintenance Fee is otherwise payable in accordance with the terms of this Agreement). Annual Maintenance Fees are due and payable (without invoice) within thirty (30) calendar days of each anniversary of the Effective Date until the first Sale. The Annual Maintenance Fees will not reduce the amount of any other payment provided for in this Article IV; and

(d) A running tiered royalty on Net Sales of all Licensed Products in the Licensed Territory as set forth in Table 4.1(d) will apply:

Table 4.1(d)

Aggregate Net Sales in any calendar year	Royalty Rate on Net Sales
Net Sales up to and including $15 million	[*]%
Net Sales greater than $15 million	[*]%

If neither a particular Licensed Product nor the use thereof is covered by a Valid Claim in the United States at the time that such Licensed Product is Sold in the United States, then for so long as there is no such Valid Claim during the Royalty Term in the United States, the Royalty Rate on the Net Sales of such Licensed Product Sold in the United States shall be reduced by twenty-five percent (25%), such that the rates set forth in Table 4.1(d) will be, respectively, [*]% and [*]%; and

(e) After the first Sale, minimum annual royalties ("**Minimum Annual Royalties**") of $100,000.00, increasing by $25,000.00 each year thereafter (for example, the Minimum Annual Royalties due for the second, third, and fourth anniversaries of the Effective Date are $125,000.00, $150,000.00, and $175,000.00, respectively, etc.), due and payable (without invoice) within thirty (30) calendar days of the first and subsequent anniversaries of the Effective Date which follows the first Sale; provided, however, that in the event that there is less than a twelve (12) month period between the first Sale, and the first anniversary of the Effective Date which follows the first Sale, then Licensee shall pay the following:

(i) the Annual Maintenance Fee due for that year multiplied by the fraction A/C, where A is the number of months between the anniversary of the Effective Date preceding the first Sale and the first Sale, and C is twelve (12); and

(ii) the Minimum Annual Royalties multiplied by the fraction B/C, where B is the number of months between the first Sale and the first anniversary of the Effective Date which follows the first Sale, C is twelve (12), and A + B = twelve (12).

Running royalties accrued under Section 4.1(d) and paid to MD Anderson during the one-year period preceding an anniversary of the Effective Date shall be credited against the Minimum Annual Royalties due on that anniversary date; and

(f) The following one-time milestone payments:

Table 4.1(f)

Milestone Events for Licensed Products	Milestone Payment
Regulatory Approval of a Licensed Product in the United States	$[*]
Regulatory Approval of a Licensed Product in a country within the European Union	$[*]
Net Sales collectively exceed $25,000,000.00	$[*]
Net Sales collectively exceed $50,000,000.00	$[*]
Net Sales collectively exceed $100,000,000.00	$[*]

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

Licensee shall notify MD Anderson in writing immediately upon achievement of any of the foregoing milestones. Each of the foregoing milestone payments shall be made by Licensee to MD Anderson (without invoice) within forty-five (45) calendar days of achieving the milestone event and shall not reduce the amount of any other payment provided for in this Article IV. Notwithstanding anything to the contrary, each milestone payment is payable only once under this Agreement, with respect to the initial accomplishment thereof, regardless of the number of Licensed Products or the number of times such milestone may be achieved; and

(g) a payment of $[*] upon the first three (3) Change of Control events effected after the Effective Date and upon each and every Assignment ("**Transaction Value Payout**"). Such payment shall be due and payable within forty-five (45) days following the closing of such Change of Control.

4.2 Unless otherwise provided, all such payments are payable within one hundred and five (105) calendar days or contemporaneously with submission of information relating thereto to the Securities Exchange Commission (whichever is earlier) after March 31, June 30, September 30, and December 31 of each year during the term of this Agreement, at which time after first Sale Licensee will also deliver to MD Anderson a true and accurate report, giving such particulars of the business conducted during the preceding three (3) calendar months under this Agreement as necessary for MD Anderson to account for Licensee's payments hereunder. This report will include pertinent data, including, but not limited to each of the following:

(a) The accounting methodologies used to account for and calculate the items included in the report and any differences in such accounting methodologies used by Licensee since the previous report;
(b) A list of Licensed Products produced or provided for the three (3) preceding calendar months;
(c) The total quantities of Licensed Products produced or provided;
(d) The total Sales;
(e) The calculation of Net Sales;
(f) The royalties so computed and due MD Anderson by the Royalty Rate on Net Sales listed in Table 4.1(d) and/or Minimum Annual Royalties; and
(g) All other amounts due MD Anderson herein.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

Simultaneously with the delivery of each such report, Licensee agrees to pay MD Anderson the amount due, if any, for the period of such report. These reports are required even if no payments are due.

4.3 For as long as Licensed Products are being sold or distributed and for one (1) year thereafter, Licensee agrees to keep complete and accurate records of its Sales and Net Sales in sufficient detail to enable the royalties and other payments due hereunder to be determined. Licensee agrees to permit a mutually agreeable, nationally recognized independent accounting firm who has signed a non-disclosure agreement reasonably acceptable to Licensee, at MD Anderson's expense, to examine only those of Licensee's books, ledgers, and records hereunder at a mutually agreed upon time during regular business hours, but no more than once per calendar year and only after MD Anderson has provided Licensee with 30 days' prior written notice, for the purpose of and to the extent necessary to verify the accuracy of royalty payments, other payments, and reports required pursuant to Section 4.2. All written reports, summaries thereof, and any correspondence related to any such audit shall be Confidential Information of Licensee. If any amounts due MD Anderson are determined to have been underpaid in an amount equal to or greater than five percent (5%) of the total amount due during the period so examined, then Licensee will pay the reasonable, documented out-of-pocket cost paid by MD Anderson for the examination. Licensee shall pay accrued interest at 1% per month on any and all late payments under this Agreement (regardless of whether the deficiency is identified by audit or otherwise), with such interest commencing on the date after the due date.

4.4 All amounts payable hereunder by Licensee shall be made in United States Dollar denominated funds, free and clear and without any deduction, set-off, or reduction for or on account of any tax, levy, impost, duty, charge, fee or withholding of any nature now or hereafter imposed by any governmental, fiscal or other authority.

Payments shall be by checks made payable to The University of Texas M. D. Anderson Cancer Center, and sent by United States mail to Box 4390, Houston, Texas 77210-4390, or by wire transfer to:

[*]
SWIFT: [*]
ABA ROUTING NO: [*] (wire)
ABA ROUTING NO: [*] (ACH)
ACCOUNT NAME: [*]
ACCOUNT NO.: [*]
REFERENCE: include title and Effective Date of Agreement and type of payment (e.g., license upfront fee, milestone payment, royalty, maintenance fee, etc.) and list applicable patent/application identified by MD Anderson reference number and patent number or application serial number.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

4.5 No payments due or royalty rates owed under this Agreement will be reduced as the result of co-ownership of Licensed Subject Matter by Board and another party, including, but not limited to, Licensee.

4.6 If payment requires delivery of an invoice, then MD Anderson's delay in providing an invoice shall not excuse or waive any payment obligation of Licensee, but the deadline for Licensee's payment shall be extended by the period of such delay. An invoice shall be deemed to be delivered to Licensee if transmitted to Licensee's address in Section 14.2. Any failure by Licensee to update its billing address shall not excuse timely payment.

V. Patents and Inventions

5.1 MD Anderson shall be responsible for filing, prosecution and maintenance of patent applications and patents within the Patent Rights. MD Anderson shall instruct such patent counsel to furnish Licensee with copies of all substantive correspondence with patent offices, and shall give Licensee the opportunity to provide comments on and make requests of MD Anderson concerning the filing, prosecution and maintenance of the Patent Rights, which comments and requests shall not be unreasonably refused. If both parties agree that a new patent application should be filed for Licensed Subject Matter, MD Anderson will prepare and file each such appropriate patent application, and Licensee will pay the related Patent Expenses. If Licensee notifies MD Anderson in writing that it does not intend to pay for the preparation, filing, prosecution, or maintenance of any patent or patent application within the Patent Rights ("**Abandoned Patent Rights**"), then MD Anderson may, in its sole discretion, elect to file, not file, continue prosecution or maintenance, or abandon such patent application or patent at its own expense and shall notify Licensee of its decision. Licensee's rights and obligations in any Abandoned Patent Rights shall terminate immediately upon MD Anderson's notification to Licensee of such election, but Licensee's rights in all other Patent Rights shall remain unaffected. System, Board, or MD Anderson shall provide written notice ("Abandonment Notice") to Licensee prior to abandoning prosecution or maintenance of any patent or patent application included in the Patent Rights. MD Anderson may not abandon any such Patent Right without express written consent of Licensee, such consent must be provided within ten (10) days. Notwithstanding the foregoing, MD Anderson may abandon such Patent Rights if Licensee (a) is delinquent in its payment by thirty (30) or more days with respect to any invoiced Patent Expenses or other invoiced payment obligation hereunder and (b) has not cured such delinquency after within thirty (30) calendar days after receiving written notice pursuant to Section 14.2 from MD Anderson of such delinquency.

5.2 Licensee shall reasonably cooperate with MD Anderson regarding all patent prosecution deadlines, including without limitation any deadlines imposed by the Bayh-Dole Act or modifications or amendments thereto.

5.3 The parties agree that they share a common legal interest to get valid, enforceable patents and that Licensee will keep all privileged information received pursuant to this Section confidential.

5.4 If Licensee is delinquent with respect to any invoiced Patent Expenses or other invoiced payment obligation hereunder and has not cured such delinquency after within thirty (30) calendar days after receiving written notice pursuant to Section 14.2 from MD Anderson of such delinquency, then Board, MD Anderson, and the counsel prosecuting licensed patents and patent applications shall have no obligation to confer or otherwise communicate with, or provide any information to, Licensee under this Article V of this Agreement unless and until Licensee is no longer in arrears on all payments and obligations under this Agreement.

VI. Infringement by Third Parties

6.1 Licensee shall have the exclusive first and primary right, but not the obligation, to institute, prosecute, and control any action or proceeding with respect to the infringement of any patent exclusively licensed hereunder by third parties in the Licensed Field within the Licensed Territory, with mutually agreeable counsel on any matter where such counsel represents Board or MD Anderson, and Licensee and such counsel agree to follow all required procedures of the Texas Attorney General regarding retention of outside counsel for state entities. Licensee shall be free to enter into a settlement, consent judgment, or other voluntary disposition with respect to any such action, provided that any settlement, consent judgment or other voluntary disposition thereof shall be subject to approval by Board and/or MD Anderson, if so required under any policy, rule or regulation of MD Anderson and/or Board, or any law of the State of Texas, which approval shall not be unreasonably withheld or explicitly rejected, with any such rejection to be accompanied by a reasonably detailed explanation for such rejection. In the event approval by Board is required, M D Anderson's Office of Technology Commercialization shall endeavor to obtain such approval consistent with Board's requirements and practices. Any recovery for actual damages or punitive or enhanced damages shall first be reimbursed to Licensee for its documented, third-party expenses in enforcing the Patent Rights and amounts actually reimbursed by Licensee to MD Anderson under this Section 6.1; any amounts in excess thereof shall be shared by Licensee with MD Anderson as follows: [*]% of such recovery shall be provided to MD Anderson and [*]% shall be retained by Licensee. Licensee must notify MD Anderson in writing of any potential infringement in the Licensed Field within the Licensed Territory within thirty (30) calendar days of knowledge thereof. MD Anderson agrees to its normal and customary efforts to monitor for any potential infringement in the Licensed Field within the Licensed Territory, and MD Anderson must notify Licensee in writing of any potential infringement in the Licensed Field within the Licensed Territory within thirty (30) calendar days of the MD Anderson Office of Technology Commercialization's knowledge thereof. If Licensee does not file suit against a substantial infringer in the Licensed Field within the Licensed Territory within six (6) months of Licensee's knowledge thereof, then Board or MD Anderson may, at its sole discretion upon sixty (60) calendar days' notice, enforce any patent licensed hereunder on behalf of itself and Licensee, with MD Anderson retaining all recoveries from such enforcement; provided, however, that MD Anderson shall first consult with Licensee and shall not initiate a suit or other action if Licensee reasonably believes there is significant risk that such suit or action would jeopardize its rights under the Agreement.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

VII. Patent Marking

7.1 Licensee agrees that all packaging containing individual Licensed Product(s), documentation therefor, and, when possible, actual Licensed Product(s) sold by Licensee will be appropriately marked with the number of any applicable patent(s) licensed hereunder in accordance with each country's patent laws, including Title 35, United States Code, to the extent such marking is necessary or required to fully preserve Patent Rights in each such country or the right to recover damages for infringement thereof.

VIII. Indemnification and Insurance

8.1 LICENSEE AGREES TO HOLD HARMLESS AND INDEMNIFY BOARD, SYSTEM, MD ANDERSON, THEIR REGENTS, OFFICERS, EMPLOYEES, STUDENTS AND AGENTS (THE "UT INDEMNITEES") FROM AND AGAINST ANY THIRD-PARTY CLAIMS, DEMANDS, OR CAUSES OF ACTION WHATSOEVER, COSTS OF SUIT AND REASONABLE ATTORNEY'S FEES (INCLUDING WITHOUT LIMITATION, THOSE COSTS ARISING ON ACCOUNT OF ANY INJURY OR DEATH OF PERSONS OR DAMAGE TO PROPERTY) CAUSED BY, OR ARISING OUT OF, OR RESULTING FROM, THE EXERCISE OR PRACTICE BY LICENSEE, ITS OFFICERS, ITS AFFILIATES OR THEIR OFFICERS, EMPLOYEES, AGENTS OR REPRESENTATIVES OF THE RIGHTS GRANTED HEREUNDER, EXCEPT TO THE EXTENT CAUSED BY (1) ANY GROSS NEGLIGENCE OR WILLFUL MISCONDUCT ON THE PART OF ANY UT INDEMNITEE, (2) ANY BREACH OF THIS AGREEMENT BY BOARD OR MD ANDERSON, OR (3) ANY VIOLATION OF LAW BY BOARD OR MD ANDERSON.

8.2 IN NO EVENT SHALL LICENSEE, BOARD, SYSTEM, OR MD ANDERSON BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF, OR IN CONNECTION WITH, THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER BOARD, SYSTEM OR MD ANDERSON KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES.

8.3 LICENSEE'S OBLIGATIONS TO HOLD HARMLESS AND INDEMNIFY THE UT INDEMNITEES IN SECTION 8.1 AND THE LIMITATION OF LIABILITY IN SECTION 8.2 SHALL INCLUDE, BUT ARE NOT LIMITED TO, ANY CLAIM ALLEGING STRICT STATUTORY LIABILITY, OR PRODUCT DEFECT LIABILITY THAT ARISES OUT OF, RELATES TO, IS CAUSED IN WHOLE OR IN PART BY, OR RESULTS FROM THE USE OR SALE OF ANY TANGIBLE MATERIALS (INCLUDING BIOLOGICAL MATERIALS) PROVIDED TO LICENSEE BY BOARD OR MD ANDERSON UNDER OR IN CONNECTION WITH THIS AGREEMENT OR PRODUCTS USED OR SOLD BY LICENSEE.

8.4 Beginning at the time when any Licensed Subject Matter or any Licensed Product is being distributed or sold (including for the purpose of obtaining regulatory approvals) by Licensee or its Affiliate(s), Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable and appropriate amounts with respect to Licensed Products being Sold, and Licensee shall use reasonable efforts to have the Board, System, MD Anderson, their Regents, officers, employees, students and agents named as additional insureds. Such commercial general liability insurance shall provide: (i) product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification under this Agreement; and (iii) coverage for litigation costs. The minimum amounts of insurance coverage required herein shall not be construed to create a limit of Licensee's liability with respect to its indemnification under this Agreement.

8.5 Licensee shall provide MD Anderson with written evidence of such insurance within thirty (30) calendar days of its procurement. Additionally, Licensee shall provide MD Anderson with written notice of at least fifteen (15) calendar days prior to the cancellation, non-renewal or material change in such insurance.

8.6 Licensee shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (i) the period that any Licensed Subject Matter developed pursuant to this Agreement is being commercially distributed or sold by Licensee, its Affiliate(s), or agent(s) of Licensee; and (ii) the five (5) year period immediately after such period.

IX. Use of Name

9.1 Licensee will not use the name of (or the name of any employee of) MD Anderson, System or Board in any advertising, promotional or sales literature, on its Web site, or for the purpose of raising capital without the advance written consent of Board secured through:

The University of Texas
M. D. Anderson Cancer Center
Legal Services, Unit 1674
P.O. Box 301407
Houston, TX 77230-1407

Notwithstanding the above, Licensee may use the name of (or name of employee of) MD Anderson, System, or Board in routine business correspondence, or as needed in appropriate regulatory submissions without written consent.

9.2 Neither Board, System, nor MD Anderson may use the name of Licensee (or the name of any Affiliate or employee thereof) in any advertising, promotional or sales literature, or on its Web site, or for the purpose of raising capital without the advance written consent of Licensee.

Notwithstanding the above, Board, System, and MD Anderson may use the name of (or name of employee of) Licensee, in routine business correspondence, or as needed in appropriate regulatory submissions without written consent.

X. Confidential Information and Publication

10.1 MD Anderson and Licensee each agree that all information disclosed by one party to the other party in connection with this Agreement ("**Confidential Information**"): (i) is to be received in strict confidence, (ii) is to be used only for the purposes of this Agreement, and (iii) will not be disclosed by the recipient party, its agents or employees without the prior written consent of the disclosing party, except to the extent that the recipient party can establish by competent written proof that such information:

(a) was in the public domain at the time of disclosure;

(b) later became part of the public domain through no act or omission of the recipient party, its employees, agents, successors or assigns;

(c) was lawfully disclosed to the recipient party without obligation of confidentiality or limitation on use by a third party who had the lawful right to disclose such information and who did not obtain such information under an obligation of confidentiality to either party;

(d) was already in the possession of the recipient party at the time of disclosure to recipient; or

(e) was independently developed by the recipient party without the knowledge, use, or benefit of the disclosing party's confidential information.

Notwithstanding the foregoing, all reports provided by Licensee and all information accessed or learned in connection with audits conducted under this Agreement shall be deemed Licensee's Confidential Information.

10.2 Each party's obligation of confidence hereunder will be fulfilled by using at least the same degree of care with the disclosing party's Confidential Information as it uses to protect its own Confidential Information, but always at least a reasonable degree of care. This obligation will exist while this Agreement is in force and for a period of three (3) years thereafter.

10.3 MD Anderson reserves the right to publish the general scientific findings from its research related to Licensed Subject Matter, provided that it does not disclose Licensee's Confidential Information. MD Anderson will submit the manuscript of any such proposed publication to Licensee at least thirty (30) calendar days before publication, and Licensee shall have the right to review and comment upon the publication in order to protect Licensee's Confidential Information. MD Anderson will incorporate Licensee's reasonable comments in the proposed publications, provided such modifications do not materially change the scientific content or conclusions. Upon Licensee's request, publication may be delayed up to sixty (60) additional calendar days to enable Licensee to secure adequate intellectual property protection of Licensee's Confidential Information that would otherwise be affected by the publication. Notwithstanding the foregoing, nothing in this Agreement shall require MD Anderson or Board to refrain from publishing any information if doing so would (a) cause MD Anderson or Board to violate any export control laws or laws that provide tax-exempt status for any bonds issued by MD Anderson or The University of Texas System, or (b) result in the inapplicability to MD Anderson or The University of Texas System of the fundamental research exclusion or exemption from U.S. export control laws for such information.

10.4 In the event that the recipient party is required to disclose the disclosing party's Confidential Information under operation of applicable law, regulation, or order of a court or governmental administrative body having competent jurisdiction, the recipient party shall, to the extent practicable, provide the disclosing party reasonable notice of such potential disclosure so that that the disclosing party may seek a protective order or other appropriate protection or legal relief to prevent or limit such disclosure. If, in the absence of, or pursuant to the terms of, such protection or legal relief, the recipient party is nonetheless required by applicable law, regulation, or order of a court or governmental administrative body having competent jurisdiction to disclose any portion of the disclosing party's Confidential Information, the required disclosure shall be permitted under this Agreement but shall be limited to only that portion of the disclosing party's Confidential Information for which disclosure is so required.

10.5 The parties shall not make any public disclosure regarding this Agreement, except (a) if such disclosure has been expressly approved by the other Party (such approval not to be unreasonably withheld, conditioned or delayed), or (b) if advised by counsel to issue such disclosure in order to comply with applicable laws or a similar regulatory agency in another applicable country or of any stock exchange of other securities trading institution.

XI. Assignment

11.1 This Agreement may not be assigned by Licensee, whether by assignment, by merger, by operation of law, or by any other transfer, without the prior written consent of MD Anderson; provided, however, Licensee may assign this Agreement without such consent (A) to any Affiliate of Licensee, or (B) in connection with a Change of Control. For any assignment (including without limitation, an assignment from the Licensee to one of its Affiliates) to be effective: (a) other than solely with respect to an assignment from Licensee to an Affiliate, the Licensee must timely pay MD Anderson the Transaction Value Payout specified in Section 4.1, unless waived by MD Anderson, in its sole discretion; and (b) the assignee (including any Affiliate of Licensee) must assume in writing (a copy of which writing will be provided to MD Anderson) all of Licensee's interests, rights, duties, and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if the assignee were the original party (i.e., the Licensee) to the Agreement. Notwithstanding such assignment, with respect to an assignment by Licensee to one of its Affiliates, the original Licensee (together with any Affiliate to which this Agreement is assigned) shall remain responsible and liable for all of the "Licensee's" responsibilities and liabilities under this Agreement. For the avoidance of doubt, if this Agreement is assigned to one of Licensee's Affiliates in accordance with this Section 11.1, such Affiliate shall also be deemed to be a "Licensee" under this Agreement, and such Affiliate of Licensee shall also be liable for all responsibilities, obligations, and liabilities of Licensee under this Agreement.

11.2 Any attempt to assign this Agreement by Licensee in violation of Section 11.1 is null and void without MD Anderson's prior written consent.

XII. Term and Termination

12.1 Subject to Sections 12.3 and 12.4 hereinbelow, the term of this Agreement is from the Effective Date until the last to occur of: (a) the expiration of all patents issued under Patent Rights (if any) and the cancellation, withdrawal, or express abandonment of all patent applications under Patents Rights (if any), or (b) the date that is the fifteenth (15th) anniversary of the Effective Date.

12.2 Any time after four (4) years from the Effective Date, Board or MD Anderson has the right to eliminate any country or jurisdiction from the Licensed Territory if Licensee, within ninety (90) calendar days after receiving written notice from MD Anderson of the intended termination, fails to provide written evidence satisfactory to MD Anderson that Licensee has commercialized or is actively and effectively attempting to commercialize a licensed invention in such country or jurisdiction. The following definitions apply to Section 12.2: (a) "commercialized" means having Sales in such jurisdiction; and (b) "actively and effectively attempting to commercialize" means having an effective, ongoing and active research, development, manufacturing, marketing or sales program as appropriate, directed toward obtaining regulatory approval, and/or production and/or Sales in any jurisdiction, and providing plans acceptable to MD Anderson, in its sole discretion, to commercialize licensed inventions in the jurisdiction(s) in which MD Anderson intends to terminate.

12.3 Subject to any rights herein which survive termination, this Agreement will earlier terminate in its entirety:

(a) Subject to Section 12.3(f), upon thirty (30) calendar days written notice from MD Anderson, if Licensee breaches or defaults on the payment or report obligations of Article IV (excluding the license documentation fee specified in Section 4.1(b), for which no cure period applies), unless, before the end of such thirty (30)-calendar day notice period ("Notice Period"), Licensee has cured the default or breach, and so notifies MD Anderson, stating the manner of the cure, provided however any cure of breach of use of name obligations of Article IX shall be to MD Anderson's satisfaction; provided further that the parties agree that breach or default on a payment obligation (other than failure to pay the license documentation fee specified in Section 4.1(b)), is cured by Licensee's payment within the Notice Period of past due amounts related to such breach or default;

(b) immediately, upon written notice from MD Anderson, if Licensee fails to timely pay the license upfront fee specified in Section 4.1(b);

(c) upon ninety (90) calendar days written notice from MD Anderson if Licensee materially breaches or defaults on any other obligation under this Agreement, unless, before the end of such ninety (90) calendar-day notice period, Licensee has cured the default or breach and so notifies MD Anderson, stating the manner of the cure;

(d) at any time by mutual written agreement between Licensee and MD Anderson upon one hundred eighty (180) calendar days written notice to all parties and subject to any terms herein which survive termination;

(e) In the event that Licensee (or its Affiliate) brings an action, or participates as an adverse party in any action, before any court, agency or tribunal seeking to invalidate or otherwise challenge the enforceability of or Board's ownership of any patent included in the Patent Rights, then MD Anderson may immediately terminate this Agreement upon written notice to Licensee and with no opportunity for Licensee to cure. Any dispute regarding the validity, enforceability or ownership of any patent included in the Patent Rights shall be litigated in the courts located in Houston, Texas, and Licensee agrees not to challenge personal jurisdiction in that forum. To the extent that Licensee unsuccessfully challenges, or participates as an adverse party in an action that unsuccessfully challenges, the validity or enforceability of any patent included in the Patent Rights, Licensee agrees to reimburse MD Anderson and Board for all costs and fees (including attorney's fees) paid by MD Anderson and Board in defending against such challenge. Licensee understands and agrees that, in the event Licensee successfully challenges the validity or enforceability of any patent included in the Patent Rights, all payments or other consideration made or otherwise provided by Licensee to MD Anderson prior to a final, non-appealable adjudication of invalidity and/or unenforceability shall be non-refundable. The obligations of this Section shall survive the expiration or termination of this Agreement;

(f) notwithstanding Section 12.3(a), upon thirty (30) calendar days written notice from MD Anderson if Licensee has defaulted or been late on its undisputed payment obligations pursuant to the terms of this Agreement on any two (2) occasions in a twenty-four (24) month period and subsequently fails to make an undisputed payment obligation more than fifteen (15) calendar after receiving notice from MD Anderson regarding such failure; or

(g) upon one hundred eighty (180) calendar days written notice from Licensee to MD Anderson.

12.4 Upon termination of this Agreement:

(a) nothing herein will be construed to release either party of any obligation maturing prior to the effective date of the termination;

(b) Licensee covenants and agrees to remain bound by the provisions of Articles VIII (Indemnification and Insurance), IX (Use of Board and MD Anderson's Name) and X (Confidential Information and Publication) of this Agreement; and

(c) Licensee agrees to cease and desist any use and all Sales of the Licensed Subject Matter and Licensed Products upon termination of this Agreement; provided, however, Licensee and its Affiliates shall have the right, subject to Licensee's payment of royalties as required under Article 4, to Sell any finished Licensed Products or Licensed Products in inventory or in the process of manufacture as of the date this Agreement is terminated (the "**Termination Date**") for the twelve month period beginning on the Termination Date ("**Sell-Down Period**"). The reporting and audit provisions of Article 4 shall apply to any Sales of Licensed Products made during such Sell-Down Period.

XIII. Warranty: Superior-Rights

13.1 Except for the rights, if any, of the Government of the United States of America ("**Government**") as set forth below, Board represents and warrants that, to the knowledge of the MD Anderson Office of Technology Commercialization, (a) Board is the sole owner of the entire right, title, and interest in and to Licensed Subject Matter, (b) Board has the right, power, and authority to grant licenses thereunder, (c) Board has not knowingly granted licenses thereunder to any other entity that would restrict rights granted hereunder except as stated herein, and (d) neither the execution of this Agreement nor the performance of Board's or MD Anderson's obligations hereunder will constitute a breach under the terms and provisions of any other agreement to which MD Anderson or Board is a party.

13.2 Licensee understands that the Licensed Subject Matter may have been developed under a funding agreement with the Government and, if so, that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to the Government's rights under any such agreement and any applicable law or regulation. To the extent that there is a conflict between any such agreement, applicable law or regulation and this Agreement, the terms of such Government agreement, applicable law or regulation shall prevail. Licensee agrees that Licensed Products used or Sold in the United States will be manufactured substantially in the United States, unless a written waiver is obtained in advance from the Government.

13.3 LICENSEE UNDERSTANDS AND AGREES THAT BOARD AND MD ANDERSON, BY THIS AGREEMENT, MAKE NO REPRESENTATION AS TO THE OPERABILITY OR FITNESS FOR ANY USE, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, AND/OR BREADTH OF THE LICENSED SUBJECT MATTER. BOARD AND MD ANDERSON, BY THIS AGREEMENT, ALSO MAKE NO REPRESENTATION AS TO WHETHER ANY PATENT COVERED BY PATENT RIGHTS IS VALID OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY BOARD OR MD ANDERSON IN THE LICENSED FIELD, NOR DO BOARD AND MD ANDERSON MAKE ANY REPRESENTATION THAT THE INVENTIONS CONTAINED IN PATENT RIGHTS DO NOT INFRINGE ANY OTHER PATENTS NOW HELD OR THAT WILL BE HELD BY OTHERS OR BY BOARD.

13.4 Licensee, by execution hereof, acknowledges, covenants and agrees that Licensee has not been induced in any way by Board, System, MD Anderson or employees thereof to enter into this Agreement, and further warrants and represents that (a) Licensee is entering into this Agreement voluntarily; (b) Licensee has conducted sufficient due diligence with respect to all items and issues pertaining to this Agreement; and (c) Licensee has adequate knowledge and expertise, or has used knowledgeable and expert consultants, to adequately conduct such due diligence, and agrees to accept all risks inherent herein.

XIV. General

14.1 This Agreement, and all claims arising out of or relating thereto, together with any exhibits and/or fully executed amendments hereto, constitutes the entire and only agreement between the parties for Licensed Subject Matter and all other prior negotiations, representations, agreements and understandings related to the subject matter of this Agreement are superseded hereby. Neither party has relied on any such prior communication in entering into this Agreement. No agreements altering or supplementing the terms hereof will be made except by a written document signed by both parties.

14.2 Any notice required by this Agreement shall be in writing and shall be deemed to have been sufficiently given for all purposes thereof when sent by first class mail or reputable international courier (e.g., Federal Express or UPS) and shall be evidenced by the postmark at the point of mailing or by the dated delivery receipt of the courier. All notices and any correspondence respecting this Agreement shall be transmitted as follows:

To MD Anderson, if by mail:
The University of Texas M. D. Anderson Cancer Center
Strategic Industry Ventures/Office of Technology Commercialization
Unit 1669
P.O. Box 301407
Houston, Texas 77230-1407

To MD Anderson, if by courier:
The University of Texas M. D. Anderson Cancer Center
Strategic Industry Ventures/Office of Technology Commercialization
1MC9.2216
7007 Bertner Avenue
Houston, Texas 77030-3907

To Licensee by mail or courier:
Citius Pharmaceuticals, Inc.
11 Commerce Drive, First Floor
Cranford, NJ 07016
Attn: Myron Holubiak, CEO

or other addresses as may be given from time to time under the terms of this notice provision.

Communications regarding patent prosecution may be transmitted by electronic mail. For such communications to MD Anderson sent via electronic mail, the electronic mail shall be addressed or copied to patentmail@mdanderson.org.

14.3 Licensee must comply with all applicable federal, state and local laws and regulations in connection with its activities pursuant to this Agreement or Licensed Subject Matter, including U.S. Export Administration Regulations, as well as end-user, end-use, and destination restrictions applied by the United States. Licensee acknowledges that the Licensed Subject Matter is subject to U.S. export control jurisdiction.

14.4 This Agreement and all claims arising out of or relating thereto will be governed, construed and enforced in accordance with the laws of the United States of America and of the State of Texas, without regard to its conflict of law provisions. The Texas State Courts of Harris County, Texas (or, if there is exclusive federal jurisdiction, the United States District Court for the Southern District of Texas) shall have exclusive jurisdiction and venue over any dispute arising out of this Agreement, and Licensee consents to the jurisdiction and venue of such courts and hereby explicitly waives the rights to any other venue to which it might be entitled by cause of action, domicile or otherwise.

14.5 Notwithstanding the foregoing, to the extent that Chapter 2260, Texas Government Code, as it may be amended from time to time ("Chapter 2260"), is applicable to this Agreement, Licensee acknowledges and agrees that the dispute resolution process provided for in Chapter 2260 shall be Licensee's sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Board and/or MD Anderson or the State of Texas.

14.6 Failure any party to enforce a right under this Agreement will not act as a waiver of right or the ability to later assert that right relative to the particular situation involved.

14.7 Headings included herein are for convenience only and will not be used to construe this Agreement. The Parties acknowledge and agree that both Parties substantially participated in negotiating the provisions of this Agreement; therefore, both Parties agree that any ambiguity in this Agreement shall not be construed more favorably toward one Party than the other Party, regardless of which Party primarily drafted this Agreement.

14.8 If any provision of this Agreement is for any reason found to be invalid or unenforceable, such provision shall be interpreted to fulfill its intended purpose to the maximum extent permitted by applicable law and all other provisions of this Agreement nevertheless will remain enforceable.

14.9 If Licensee desires to sponsor research for or related to the Licensed Subject Matter, Licensee (a) will notify MD Anderson in writing of all opportunities to conduct this sponsored research (including clinical trials, if applicable), (b) will solicit research and/or clinical proposals from MD Anderson for this purpose, and (c) will give good faith consideration to funding the proposals at MD Anderson.

14.10 This Agreement may be executed in one (1) or more counterparts, by original, facsimile or PDF signature, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature. In the event signatures are exchanged by facsimile and/or in ".pdf" format, each party shall thereafter promptly provide an original signature page to the other party.

14.11 MD Anderson, as an agency of the State of Texas and a member institution of The University of Texas System, is subject to the constitution and laws of the State of Texas and, under the constitution and laws of the State of Texas, possesses certain rights and privileges, is subject to certain limitations and restrictions, and only has such authority as is granted under the constitution and laws of the State of Texas. Notwithstanding anything to the contrary herein, nothing in this Agreement shall obligate The University of Texas System, The Board of Regents of The University of Texas System, MD Anderson, or any other agency of The State of Texas to join, or permit the use of its name or otherwise participate, as a litigant in any litigation or adversarial judicial proceeding. Moreover, notwithstanding the generality or specificity of any provision of this Agreement, the provisions of this Agreement as they pertain to MD Anderson are enforceable only to the extent authorized by the constitution and laws of the State of Texas. No party to this Agreement will be required to perform or commit any act or omission that would violate any applicable law, including the constitution and laws of the State of Texas. Nothing in this Agreement shall be deemed as a waiver by Board, System or MD Anderson of its sovereign immunity.

[Signatures Appear on Following Pages]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

BOARD OF REGENTS OF THE
UNIVERSITY OF TEXAS System, on behalf of THE
UNIVERSITY OF TEXAS M. D. ANDERSON
CANCER CENTER

By _____
Printed Name: _____
Title: _____

Date:_____

Approved as to Content:

By _____
Ferran Prat, J.D., Ph.D.
Senior Vice President
Research Administration & Industry Relations
M. D. Anderson Cancer Center

Date:_____

Licensee: **Citius Pharmaceuticals, Inc.**

By _____
Printed Name: _____
Title: _____

Date: _____

EXHIBIT I

MDA No.	Creators (Include M.D.)	IDR Title	All U.S. and foreign patent application/patent numbers (country code and serial number – only include pending or issued applications)
MDA13-011	Issam Raad, MD Joel Rosenblatt, PhD Andrew Dennis, PhD George Viola, MD Jesse Selber, MD	Method for Applying a Conformal Liquid Coating to an Implant	61/813,564 (US Prov.) PCT/US2014/034556 (PCT) 9,849,217 (US Issued) 15/820,154 (US Divisional)

Exhibit 10.2

FIRST AMENDMENT TO PATENT AND TECHNOLOGY LICENSE AGREEMENT

THIS FIRST AMENDMENT TO PATENT AND TECHNOLOGY LICENSE AGREEMENT ("AMENDMENT") is made on this 15th day of October, 2015, by and between Novel Anti-Infective Technologies, LLC, a Texas limited liability corporation having a principal place of business located at 4207 Clearwater Ct., Missouri City, TX 77459 ("LICENSOR") and Leonard-Meron Biosciences, Inc., a Delaware corporation having a principal place of business located 11 Commerce Drive, First Floor, Cranford, NJ 07016 ("LICENSEE").

RECITALS

A. LICENSOR and LICENSEE entered into a Patent and Technology License Agreement dated May 14, 2014 (the "SUBLICENSE") pursuant to which LICENSOR granted LICENSEE a sublicense to certain rights licensed to LICENSOR pursuant to a Patent and Technology License Agreement dated as of May 7, 2014 (the "SYSTEM LICENSE AGREEMENT"), with THE BOARD OF REGENTS ("BOARD") of THE UNIVERSITY OF TEXAS SYSTEM ("SYSTEM"), an agency of the State of Texas, on behalf of THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER ("UTMDACC"), a member institution of SYSTEM.

B. LICENSOR has entered into an amendment to the SYSTEM LICENSE AGREEMENT titled "Amendment No. 3 to the Patent and Technology License Agreement" dated October 7, 2015 which grants LICENSOR certain rights to the technology identified in UTMDACC's invention disclosure MDA14-098;

C. LICENSOR and LICENSEE now desire to amend the SUBLICENSE to include in the "PATENT RIGHTS," as defined in the SUBLICENSE, the rights of LICENSOR in MDA 14-098.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the parties agree as follows:

1. EXHIBIT 1 Amendment. EXHIBIT 1 to the SUBLICENSE is hereby amended and restated to read in its entirety as provided in EXHIBIT 1 attached to this AMENDMENT.

2. EXHIBIT 2 Amendment. EXHIBIT 2 to the SUBLICENSE is hereby amended by adding "and MDA 14-098" after "MDA03-038" in the first line.

3. No Further Amendment. Except as expressly amended hereby, the SUBLICENSE shall remain in full force and effect. This AMENDMENT shall be construed to be, and interpreted as, a part of the SUBLICENSE.

4. Counterparts. This AMENDMENT may be executed in two or more counterparts, each of which when executed shall be deemed to be an original, and all of which together shall be considered one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party. For purposes of this AMENDMENT facsimile signatures or signatures by other electronic form of transfer, including PDF file, shall be deemed originals.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this AMENDMENT.

LEONARD-MERON BIOSCIENCES, INC.	NOVEL ANTI-INFECTIVE TECHNOLOGIES, LLC
By _____	By _____
Printed Name: Myron Holubiak	Printed Name: _____
Title: Chief Executive Officer	Title: _____

EXHIBIT 1

MDA No. (each an individual technology)	Inventors	IDR Title	U.S. and foreign patent application/patent numbers
MDA03-038	Issam I Raad, M.D.	Antimicrobials in Combination with Chelators and Ethanol for the Rapid Eradication of Microorganisms Embedded in Biofilm	U.S. Patent No.: 7,601,731; EP Serial No.: 04754538.9; CA Serial No.: 2,528,522; U.S. Serial No.: 13/095,262; U.S. Serial No.: 13/621,628
MDA14-098	Issam I Raad, M.D., Joel Rosenblatt, Ph.D.	Antimicrobial Catheter Lock/Flush Solutions with Enhanced Stability	None

Exhibit 10.3

Portions of this exhibit marked [*] are requested to be treated confidentially.

PATENT AND TECHNOLOGY LICENSE AGREEMENT

This AGREEMENT ("AGREEMENT") is made on this 14th day of May, 2014, by and between Novel Anti-Infective Technologies, LLC, a limited liability corporation organized and existing under the laws of the State of Texas and having a principal place of business located at 4207 Clearwater Ct., Missouri City, TX 77459 ("LICENSOR") and Leonard-Meron Biosciences, Inc., a Delaware corporation having a principal place of business located 11 Commerce Drive, First Floor, Cranford, NJ 07016 ("LICENSEE").

RECITALS

A. LICENSOR obtained, pursuant to a Patent and Technology License Agreement dated as of May 7, 2014 (the "SYSTEM LICENSE AGREEMENT"), certain patent and technology rights from THE BOARD OF REGENTS ("BOARD") of THE UNIVERSITY OF TEXAS SYSTEM ("SYSTEM"), an agency of the State of Texas, whose address is 201 West 7th Street, Austin, Texas 78701, on behalf of THE UNIVERSITY OF TEXAS M. D. ANDERSON CANCER CENTER ("UTMDACC"), a member institution of SYSTEM.

B. LICENSOR desires to have the LICENSED SUBJECT MATTER developed in the LICENSED FIELD and used for the benefit of LICENSEE, BOARD, SYSTEM, UTMDACC, the inventor(s), and the public as outlined in BOARD's Intellectual Property Policy.

C. LICENSEE wishes to obtain a license from LICENSOR to practice LICENSED SUBJECT MATTER in the LICENSED FIELD.

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, the parties agree as follows:

I. EFFECTIVE DATE

1.1 This AGREEMENT is effective as of the date written above ("EFFECTIVE DATE") which is the date fully executed by all parties.

II. DEFINITIONS

As used in this AGREEMENT, the following terms have the meanings indicated:

2.1 **AFFILIATE** means any business entity more than fifty percent (50%) owned by LICENSEE, any business entity which owns more than fifty percent (50%) of LICENSEE, or any business entity that is more than fifty percent (50%) owned by a business entity that owns more than fifty percent (50%) of LICENSEE.

2.2 **INDIVIDUAL PRODUCT** means a LICENSED PRODUCT that is distinctive from another LICENSED PRODUCT in a significant way, e.g., more than just a variation in color or size. By way of example, and not by way of limitation, if two LICENSED PRODUCTS require individual REGULATORY APPROVAL (excluding products that differ only in color, dosage and size) each shall be considered a different INDIVIDUAL PRODUCT. By way of further example, if two LICENSED PRODUCTS have substantially different, non-overlapping uses, each shall be considered a different INDIVIDUAL PRODUCT. If a LICENSED PRODUCT is determined to be a new INDIVIDUAL PRODUCT under the SYSTEM LICENSE AGREEMENT such determination shall govern for the purposes of this AGREEMENT.

2.3 **LICENSED FIELD** means the field of use identified in Exhibit 2.

2.4 **LICENSED PRODUCT(S)** means any product or service sold by LICENSEE or its AFFILIATES or their sublicensees comprising LICENSED SUBJECT MATTER pursuant to this AGREEMENT. For clarity, LICENSED PRODUCTS will include such product and services sold in any jurisdiction in the TERRITORY even if no PATENT RIGHTS exist or are pending in that jurisdiction.

2.5 **LICENSED SUBJECT MATTER** means the inventions and discoveries covered by the PATENT RIGHTS or TECHNOLOGY RIGHTS within the LICENSED FIELD.

2.6 **LICENSED TERRITORY** means worldwide excluding only South America.

2.7 **[RESERVED**.]

2.8 **NET SALES** means the gross revenues received by LICENSEE or its AFFILIATES or sublicensees from a SALE, less sales discounts actually granted, sales and/or use taxes actually paid, import and/or export duties actually paid, outbound transportation actually prepaid or allowed, and amounts actually allowed or credited due to returns (not exceeding the original billing or invoice amount), all as recorded by LICENSEE or its AFFILIATES or their sublicensees in their official books and records in accordance with generally accepted accounting practices and consistent with their published financial statements and/or regulatory filings with the United States Securities and Exchange Commission, if any. For clarity, it is understood and agreed that, with respect to NET SALES of a LICENSED PRODUCT made by a sublicensee or AFFILIATE (or by a sublicensee or AFFILIATE) to a third party, the "gross revenue" figure referenced above (for purposes of calculating the amount of NET SALES subject to the royalties specified in Section 4.1(d) below) shall be the greater of: (1) the gross revenue received by LICENSEE from the sublicensee, AFFILIATE or distributor for the transfer of such LICENSED PRODUCT to the sublicensee, or AFFILIATE for resale; or (2) the gross revenue received by such sublicensee, or AFFILIATE from such third party for the transfer or disposition of such LICENSED PRODUCT to the third party. If a LICENSED PRODUCT is SOLD by LICENSEE, a sublicensee, or an AFFILIATE of either, to a distributor in which LICENSEE, any sublicensee or an AFFILIATE of either has any economic interest, including but not limited to equity or debt, or with which any of them have any other agreement, then any SALE by such distributor shall be deemed to be a SALE by such LICENSEE, sublicensee or AFFILIATE for purposes of this AGREEMENT.

2.9 **PATENT RIGHTS** means BOARD's and LICENSOR's rights in the information or discoveries described in invention disclosures, or claimed in any patents and/or patent applications, whether domestic or foreign, as identified in Exhibit 1 attached hereto, and all divisionals, continuations, continuations-in-part (to the extent the claims of such continuations-in-part are entitled to claim priority to the aforesaid patents and/or patent applications identified in Exhibit 1), reissues, reexaminations, extensions or foreign counterparts of the patents and/or patent applications identified in Exhibit 1, and any letters patent, domestic or foreign that issue thereon.

2.10 **REGULATORY APPROVAL** means the approval required by the United States Food and Drug Administration ("FDA") in the United States (or the equivalent regulatory agency or governmental authority for any country other than the United States) to market and sell a LICENSED PRODUCT for human use in the applicable country.

2.11 **REGULATORY APPROVAL FILING** means the filing or submission to the FDA (or equivalent regulatory agency or governmental authority for a country other than the United States) necessary to get REGULATORY APPROVAL to market and sell a LICENSED PRODUCT for human use in the applicable country, including, but not limited to, an IDE, 510K or IND application filed with/submitted to the FDA in the United States, or an equivalent filing or submission to an equivalent regulatory agency or governmental authority for a country other than the United States. For clarity, "REGULATORY APPROVAL FILING" means the filing or submission itself, and does not mean the actual approval which may ultimately be granted by the regulatory agency or governmental authority to actually market and sell a LICENSED PRODUCT for human use.

2.12 **ROYALTY EXPIRATION DATE** means the date that all patents within the PATENT RIGHTS have expired and all patent applications within the PATENT RIGHTS have been cancelled, withdrawn or expressly abandoned.

2.13 **SALE** or **SOLD** means the transfer or disposition of a LICENSED PRODUCT for value to a party other than LICENSEE or a ROYALTY-FREE PRACTITIONER. As used herein, "ROYALTY-FREE PRACTITIONER" means UTMDACC and the following individuals: Issam I. Raad, M.D. and Hend Hanna, M.D. ("PHYSICIAN INVENTORS"), and any partner or associate who practices medicine with one or more of the PHYSICIAN INVENTORS, but with respect to such partner or associate, only for such time as he/she is engaged in a bona fide medical practice with one or more of the PHYSICIAN INVENTORS. Notwithstanding the foregoing, the term "SALE" or "SOLD" shall not include transfers or dispositions of LICENSED PRODUCTS to third parties for no or nominal consideration in order to perform such clinical trials as are reasonably required to obtain the regulatory approval necessary to sell a LICENSED PRODUCT. In addition, the term "SALE" or "SOLD" shall not include transfer or disposition of a LICENSED PRODUCT for value to a sublicensee or AFFILIATE, unless the sublicensee or AFFILIATE is the end user of such LICENSED PRODUCT.

2.14 **SUBLICENSING CONSIDERATION** means all consideration (unless specifically excepted, below) received by LICENSEE from any sublicensee in consideration of a sublicense pursuant to Section 3.3 hereinbelow, including but not limited to, up-front payments, marketing, distribution, franchise, option, license, or documentation fees, assignment fees, bonus fees, equity, and milestone payments for milestones other than those milestones requiring a payment under Section 4.1(f) herein. SUBLICENSING CONSIDERATION shall not include patent fees paid by a sublicensee to LICENSEE as reimbursement for specific, identified patent expenses previously paid, or to be paid, by LICENSEE to LICENSOR or UTMDACC pursuant to an invoice sent to LICENSEE in accordance with Section 4.1(a), below, provided that LICENSEE has paid the amount owing under such invoice. In addition, SUBLICENSING CONSIDERATION shall not include funds paid by a sublicensee for future research to be performed by LICENSEE relating to LICENSED SUBJECT MATTER if: (a) the respective sublicense agreement expressly states that such funds are for research covering the LICENSED SUBJECT MATTER to be performed by LICENSEE after the actual date of signatory execution of the sublicense agreement; and (b) LICENSEE does in fact perform such research after execution of, and in accordance with, the sublicense agreement. For the avoidance of doubt, LICENSEE shall not deduct from SUBLICENSING CONSIDERATION: (1) any amounts received from a sublicensee as reimbursement or recoupment of research expenses incurred by LICENSEE before the actual date of full execution of the sublicense agreement by all parties thereto; (2) any overhead or indirect costs for research described in subparts (a) and (b) above; or (3) any payments by a sublicensee for LICENSEE's achievement of research or similar milestone events. Notwithstanding anything in this Agreement to the contrary, SUBLICENSING CONSIDERATION will exclude any royalty revenue and other payments made to LICENSEE based on SALES.

2.15 **TECHNOLOGY RIGHTS** means BOARD's and LICENSOR's rights in any technical information, know-how, processes, procedures, compositions, devices, methods, formulae, protocols, techniques, software, designs, drawings or data created by the inventor(s) listed in Exhibit 1 at UTMDACC before the EFFECTIVE DATE, which are not claimed in PATENT RIGHTS but that are necessary for practicing PATENT RIGHTS.

2.16 **VALID CLAIM** means a claim of: (a) any issued, unexpired patent that has not been withdrawn, abandoned, canceled or disclaimed, or revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (b) any pending patent application that that has not been cancelled, withdrawn, abandoned or finally disallowed without the possibility of appeal or refilling, and that has not been pending for more than ten (10) years from the application's file date. For purposes of clarification, if a claim in an application has been pending for more than ten (10) years from the application's file date, and a patent subsequently issues on such application containing such claim, then upon the earlier of allowance of the claim (or issuance of the patent containing such claim, the claim shall thereafter be considered a VALID CLAIM.

III. LICENSE

3.1 LICENSOR hereby grants to LICENSEE a royalty-bearing, exclusive license under LICENSED SUBJECT MATTER to manufacture, have manufactured, use, import, offer to sell and/or sell LICENSED PRODUCTS within the LICENSED TERRITORY for use within LICENSED FIELD**.** This grant is subject to the payment by LICENSEE to LICENSOR of all consideration as provided herein (on the due date, or prior to the expiration of any cure period, if applicable), and is further subject to the following rights retained by BOARD and UTMDACC to:

(a) Publish the general scientific findings from research related to LICENSED SUBJECT MATTER, subject to the terms of ARTICLE XI–Confidential Information and Publication; and

(b) Use LICENSED SUBJECT MATTER for research, teaching, patient care, and other academically-related purposes; and

(c) Transfer LICENSED SUBJECT MATTER to academic or research institutions for non-commercial research use.

3.2 LICENSEE may extend the license granted herein to any AFFILIATE provided that the AFFILIATE consents in writing to be bound by this AGREEMENT to the same extent as LICENSEE. LICENSEE agrees to deliver such contract to LICENSOR within thirty (30) calendar days following execution thereof.

3.3 LICENSEE may grant sublicenses under LICENSED SUBJECT MATTER consistent with the terms of this AGREEMENT, provided that LICENSEE shall use all commercially reasonable efforts to diligently enforce the sublicenses including, but not limited to, collecting all amounts due LICENSEE from sublicensees and taking all commercially reasonable steps to terminate any sublicense in which the sublicensee is in default on any payments owed or any other material obligations existing thereunder. If a sublicensee pursuant hereto becomes bankrupt, insolvent or is placed in the hands of a receiver or trustee, LICENSEE, to the extent allowed under applicable law and in a timely manner, agrees to use its commercially reasonable efforts to collect all consideration owed to LICENSEE and to have the sublicense agreement confirmed or rejected by a court of proper jurisdiction.

3.4 LICENSEE must deliver to LICENSOR a true and correct copy of each sublicense granted by LICENSEE, and any modification or termination thereof, within thirty (30) calendar days after execution, modification, or termination.

3.5 If this AGREEMENT is terminated pursuant to ARTICLE XIII-Term and Termination, LICENSOR agrees to accept as successors to LICENSEE, existing sublicensees in good standing at the date of termination provided that each such sublicensee consents in writing to be bound by all of the terms and conditions of the SYSTEM LICENSE AGREEMENT.

IV. LICENSE CONSIDERATION, PAYMENTS AND REPORTS

4.1 In consideration of rights granted by LICENSOR to LICENSEE under this AGREEMENT, LICENSEE agrees to pay LICENSOR the following:

(a) All out-of-pocket expenses LICENSOR is required to pay to or on behalf of UTMDACC in filing, prosecuting, enforcing and maintaining PATENT RIGHTS, and all such future expenses paid to or on behalf of UTMDACC, for so long as, and in such countries as this AGREEMENT remains in effect ("PATENT EXPENSES"). LICENSOR will invoice LICENSEE after the AGREEMENT has been fully executed by all parties for expenses incurred as of that time and on a quarterly basis thereafter. The invoiced amounts will be due and payable by LICENSEE within thirty (30) calendar days of the receipt of the invoice. Upon written request, LICENSOR shall provide LICENSEE with documentation of out-of-pocket expenses with respect to a particular invoice or invoices. Notwithstanding the foregoing, in the event that there are multiple licensees of an issued patent or a proposed or pending patent application within the PATENT RIGHTS (i.e., additional licensees to such patent or such proposed or pending patent application in other fields of use), then LICENSEE shall be obligated to pay only a pro rata share of the PATENT EXPENSES attributable to that patent or proposed or pending patent application. The pro rata share shall be calculated based on the total amount of PATENT EXPENSES attributable to that issued patent or proposed or pending patent application divided by the total number of licensees with active licenses to the patent or the proposed or pending patent application. At the time LICENSEE is sent an invoice for PATENT EXPENSES, LICENSOR shall notify LICENSEE of the total number of active licensees to such patents or proposed or pending patent applications for which such PATENT EXPENSES were incurred and shall specify the pro rata amount owed by LICENSEE for each, as applicable. In the event additional licensees to a patent or a proposed or pending patent application are added after LICENSEE has paid an invoice, LICENSEE shall not be entitled to a refund of any past payments for PATENT EXPENSES. However, the pro rata amount of prospective payments due to LICENSOR by LICENSEE for PATENT EXPENSES attributable to a patent or a proposed or pending patent application under this AGREEMENT shall be adjusted to reflect the total number of licensees with active licenses to such patent or proposed or pending patent application. It is understood and agreed that in the event that a license to an additional licensee is terminated, LICENSEE's pro rata share of PATENT EXPENSES will increase, and shall be calculated based on the total unpaid amount owed to LICENSOR for PATENT EXPENSES attributable to that patent or patent application divided by the total number of licensees with active licenses to such patent or patent application. For clarity, if LICENSEE is the only licensee of a patent or a proposed or pending patent application within the PATENT RIGHTS, LICENSEE shall be responsible for all PATENT EXPENSES attributable to such patent or proposed or pending patent application; and

(b) A nonrefundable license fee in the amount of $325,000. This fee will not reduce the amount of any other payment provided for in this ARTICLE IV, and is due and payable (with invoice) within thirty (30) calendar days after the AGREEMENT has been fully executed by all parties. This license fee is not subject to the forty-five (45) day cure period set forth in Section 13.4(b); and

(c) The following nonrefundable annual maintenance fees ("Annual Maintenance Fee(s)") due and payable (without invoice) within thirty (30) calendar days of the applicable anniversary of the EFFECTIVE DATE until the first SALE as follows:

(1) $30,000 due and payable within thirty (30) calendar days of the first anniversary of the EFFECTIVE DATE; and

(2) $45,000 due and payable within thirty (30) calendar days of the second anniversary of the EFFECTIVE DATE; and

(3) $50,000 due and payable within thirty (30) calendar days of the third anniversary of the EFFECTIVE DATE; and

(4) $75,000 due and payable within thirty (30) calendar days of the fourth anniversary of the EFFECTIVE DATE; and

(5) $90,000 due and payable within thirty (30) calendar days of the fifth and each subsequent anniversary of the EFFECTIVE DATE until the first SALE; and

(6) for the year in which the first SALE occurs, a pro-rated portion of the Annual Maintenance Fee will be paid within thirty (30) calendar days of SALE which equals the percentage of the year remaining when the first SALE occurs multiplied by $90,000; provided that this final Annual Maintenance Fee will be credited against running royalties; and

(d) A running royalty on NET SALES of LICENSED PRODUCTS, said royalty rate being calculated as follows on a per annum basis. As used in this Section 4.1(d), "per annum" means per each one year period commencing on each anniversary of the EFFECTIVE DATE:

(1) For LICENSED PRODUCTS, the royalty rate shall be [*]% of NET SALES of LICENSED PRODUCTS.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(2) In the event a LICENSED PRODUCT sold in the United States is not covered by a VALID CLAIM in the United States at the time of SALE, then LICENSEE may reduce the royalty rates specified in subsection (1) above from [*]% of NET SALES to [*]% of NET SALES of LICENSED PRODUCTS.

(3) In the event a LICENSED PRODUCT sold in a country other than the United States is not covered by a VALID CLAIM in such country of SALE at the time of such SALE, then LICENSEE may reduce the royalty rates specified in subsection (1) above from [*]% of NET SALES to [*]% of NET SALES of LICENSED PRODUCTS.

(4) In addition, with respect to NET SALES of LICENSED PRODUCTS that are not covered by a VALID CLAIM in the country of SALE at the time of SALE, if an unrelated third party (e.g., an independent third party who is not a sublicensee of or otherwise authorized by LICENSEE, any AFFILIATE, sublicensee or other entity owned or controlled by LICENSEE to make such SALE) is selling a competing product in that country that is the same or substantially the same as the LICENSED PRODUCT being sold by LICENSEE in such country and such unrelated third party sales of the competing product in that country accounts for [*] percent ([*]%) or more of aggregate sales of the LICENSED PRODUCT and competing product in such country in the preceding six (6) month period, then the running royalty in such country for such LICENSED PRODUCT shall thereafter be reduced to [*]% of NET SALES for so long as no VALID CLAIM exists, and such third party competition persists, in such country.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(e) After the first SALE of any LICENSED PRODUCT, minimum aggregate annual royalties ("Minimum Annual Royalty") due and payable (without invoice) within thirty (30) calendar days of the first and subsequent anniversaries of the EFFECTIVE DATE which follow the first SALE as follows:

(1) $100,000 due and payable within thirty (30) calendar days of the first anniversary of the EFFECTIVE DATE which follows the first SALE, provided, however, that in the event that there is less than a twelve (12) month period between the first SALE, and the first anniversary of the EFFECTIVE DATE which follows the first SALE, then LICENSEE shall pay the following as the Minimum Annual Royalty on the first anniversary of the EFFECTIVE DATE which follows the first SALE: (1) the Annual Maintenance Fee due for that year multiplied by the fraction, A/C, where A is the number of months between the anniversary of the EFFECTIVE DATE preceding the first SALE, and the first SALE, and C is twelve (12); and (2) the Minimum Annual Royalty multiplied by the fraction, B/C, where B is the number of months between the first SALE, and the first anniversary of the EFFECTIVE DATE which follows the first SALE, C is twelve (12), and A + B = twelve (12); and

(2) Thereafter, Minimum Annual Royalty shall increase by $25,000 per year up to a maximum of $150,000 (i.e., $125,000 shall be due and payable within thirty (30) calendar days of the second anniversary of the EFFECTIVE DATE which follows the first SALE; $150,000 shall be due and payable within thirty (30) calendar days of the third anniversary of the EFFECTIVE DATE which follows the first SALE, and every anniversary occurring thereafter.

Payments actually made to LICENSOR for running royalties accruing during the one year period preceding an anniversary of the EFFECTIVE DATE pursuant to Sections 4.1(d) and 4.1(i) may be credited against the Minimum Annual Royalty due on that anniversary date; and

(f) The following milestone payments, due and payable one time for the first achievement of each milestone for each INDIVIDUAL PRODUCT, regardless of whether the milestone is achieved by LICENSEE, a sublicensee or AFFILIATE and regardless of whether such milestone is subsequently achieved multiple times for an INDIVIDUAL PRODUCT:

(1) Acceptance by the FDA of a REGULATORY APPROVAL FILING submitted by LICENSEE, its AFFILIATES or SUBLICENSEES: $[*];

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(2) first SALE of a LICENSED PRODUCT by LICENSEE, its AFFILIATES or SUBLICENSEES in the United States following REGULATORY APPROVAL: $[*]

(3) cumulative NET SALES of a LICENSED PRODUCT in the U.S. exceed $[*]: [*]

(4) REGULATORY APPROVAL in Japan with respect to REGULATORY APPROVAL FILING submitted by LICENSEE, its AFFILIATES or SUBLICENSEES: $[*];

(5) REGULATORY APPROVAL in EMEA with respect to REGULATORY APPROVAL FILING submitted by LICENSEE, its AFFILIATES or SUBLICENSEES: $[*]; and

(6) REGULATORY APPROVAL in any one of the following: Canada, Australia, India, China, Taiwan, South Korea, Brazil or Russian, with respect to REGULATORY APPROVAL FILING submitted by LICENSEE, its AFFILIATES or SUBLICENSEES: $[*]

(7) cumulative NET SALES of LICENSED PRODUCTs exceed $[*]: $[*]

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(8) cumulative NET SALES of LICENSED PRODUCTs exceed $[*]: $[*]

Each of the foregoing milestone payments shall be made within thirty (30) calendar days of achievement of the applicable milestone. LICENSEE shall specify with each milestone payment the applicable milestone to which the payment pertains. The foregoing milestone payments shall not reduce the amount of any other payment provided for in this ARTICLE IV; and

(g) The following percentages of all SUBLICENSING CONSIDERATION, as defined above, will be calculated based on the status of REGULATORY APPROVAL and/or SALE of LICENSED PRODUCTS for which the SUBLICENSING CONSIDERATION is paid:

(1) [*]% of all SUBLICENSING CONSIDERATION received for United States rights on or after the EFFECTIVE DATE but prior to the earlier of: (a) the first acceptance of a REGULATORY APPROVAL FILING in the United States by the applicable regulatory agency or governmental authority for a LICENSED PRODUCT; or (b) the first SALE of a LICENSED PRODUCT in the United States; and

(2) [*]% of all SUBLICENSING CONSIDERATION received for United States rights on or after the earlier of: (a) the first acceptance of a REGULATORY APPROVAL FILING in the United States by the applicable regulatory agency or governmental authority for a LICENSED PRODUCT; or (b) the first SALE of a LICENSED PRODUCT in the United States; and

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

(3) [*]% of all SUBLICENSING CONSIDERATION received for rights outside the United States on or after the EFFECTIVE DATE but prior to the earlier of: (a) the first acceptance of a REGULATORY APPROVAL FILING outside the United States by the applicable regulatory agency or governmental authority for a LICENSED PRODUCT; (b) the first SALE of a LICENSED PRODUCT outside the United States or (c) 18 months from the Effective Date; and

(4) [*]% of all SUBLICENSING CONSIDERATION received for rights outside the United States on or after the earlier of: (a) the first acceptance of a REGULATORY APPROVAL FILING outside the United States by the applicable regulatory agency or governmental authority for a LICENSED PRODUCT; (b) the first SALE of a LICENSED PRODUCT outside the United States or (c) 18 months from the Effective Date; and

(h) a one-time Assignment Fee (in consideration for LICENSOR allowing the assignment), due and payable prior to any permitted assignment of this AGREEMENT pursuant to Section 12.1 below, in the amount of $[*]. Nothing in this Section 4.1(h) shall be construed as relieving LICENSEE of its obligations under Section 12.1, below, to obtain any necessary consent prior to assignment; and

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

4.2 Unless otherwise provided, all such payments are payable (without invoice) within thirty (30) calendar days after March 31, June 30, September 30, and December 31 of each year during the term of this AGREEMENT, at which time LICENSEE will also deliver to LICENSOR a true and accurate report, giving such particulars of the business conducted by LICENSEE, its AFFILIATES and its sublicensees, if any exist, during the preceding three (3) calendar months under this AGREEMENT as necessary for LICENSOR to account for LICENSEE's payments hereunder. This report will include pertinent data required to calculate the payments owed hereunder, including, but not limited to:

(a) the accounting methodologies used to account for and calculate the items included in the report and any differences in such accounting methodologies used by LICENSEE since the previous report; and

(b) a list of LICENSED PRODUCTS produced for the three (3) preceding calendar months categorized by the INDIVIDUAL PRODUCT and country of sale; and

(c) the total quantities of LICENSED PRODUCTS, itemized by the categories listed in Section 4.2(b); and

(d) the total SALES, itemized by the categories listed in Section 4.2(b), and the calculation of NET SALES, showing the gross revenues and all deductions; and

(e) the royalties computed and due LICENSOR, itemized by the categories listed in Section 4.2(b), and/or minimum royalties; and

(f) all consideration received from each sublicensee or assignee, itemized by the categories listed in Section 4.2(b) to the extent applicable, and the calculation of all payments due LICENSOR; and

(g) all other amounts due LICENSOR herein, and an explanation as to how such amounts were calculated.

Simultaneously with the delivery of each such report, LICENSEE agrees to pay LICENSOR the amount due, if any, for the period of such report. These reports are required after the first SALE or first receipt of consideration from a sublicensee or assignee, even if no payments are due. In addition, upon written request from LICENSOR, LICENSEE shall provide such quarterly reports prior to the first SALE.

4.3 During the term of this AGREEMENT and for one (1) year thereafter, LICENSEE agrees to keep complete and accurate records of its and its AFFILIATES' SALES and NET SALES, SUBLICENSING CONSIDERATION and its sublicensees' SALES and NET SALES, in sufficient detail to enable the royalties and other payments due hereunder to be determined. LICENSEE agrees to permit LICENSOR or its representatives, at LICENSOR 's expense, to examine LICENSEE's books, ledgers, and records during regular business hours, and upon reasonable notice, for the purpose of and to the extent necessary to verify any report required under this AGREEMENT. Such examination shall be conducted no more frequently than once every twelve (12) months. If any amounts due LICENSOR are determined to have been underpaid in an amount equal to or greater than five percent (5%) of the total amount due during the period so examined, then LICENSEE will pay the cost of the examination plus accrued interest at the highest allowable rate.

4.4 Within thirty (30) calendar days following each anniversary of the EFFECTIVE DATE, LICENSEE will deliver to LICENSOR a written progress report as to LICENSEE's (and any sublicensee's) efforts and accomplishments during the preceding year in diligently commercializing LICENSED SUBJECT MATTER in the LICENSED TERRITORY and LICENSEE's (and sublicensees') commercialization plans for the upcoming year.

4.5 All amounts payable hereunder by LICENSEE will be paid in United States funds without deductions for taxes, assessments, fees, or charges of any kind.

V. RESEARCH

5.1 LICENSOR will provide research services in the form of: (i) review and comment on the candidates for the Phase III clinical studies sponsored by LICENSEE for a Licensed Product (the "STUDIES"), (ii) consultation with regard to the conduct of the STUDIES and (iii) reviewing and providing comments and supplementary analysis of the results of the STUDIES (collectively, the "SERVICES"). As consideration for the performance of the SERVICES, LICENSEE will pay LICENSOR (i) $50,000.00 within thirty (30) days of the EFFECTIVE DATE; and (ii) $1,300.00 per patient enrolled in the STUDIES for which SERVICES are provided after the date hereof, up to a maximum of $450,000.00 The amount due per patient shall be determined and paid on July 1 and December 31 of each year. LICENSEE will provide LICENSOR the opportunity to provide the SERVICES with respect to all patients enrolled in the STUDIES after the date hereof. If the STUDIES are interrupted or halted for any reason, and then later restarted or alternative STUDIES are commenced, the payments shall immediately resume for the SERVICES provided. For the avoidance of doubt, no fees shall be due for any STUDY for which LICENSOR does not provide SERVICES. If LICENSEE breaches any of the foregoing payment obligations, and such breach is not cured within forty-five (45) days of receiving notice of such breach from LICENSOR, then LICENSOR may immediately terminate this AGREEMENT by giving written notice to LICENSEE.

LICENSEE has expressed an interest in possibly licensing additional anti-microbial technologies that LICENSOR has licensed under the SYSTEM LICENSE AGREEMENT. Any funds provided to LICENSOR pursuant to this Section that are not used to furnish the SERVICES related to the STUDIES shall be used by LICENSOR to conduct research on such other technologies. Provided, however, LICENSEE shall not be deemed to have any rights with respect to such technologies or potential license.

VI. PATENTS AND INVENTIONS

6.1 The SYSTEM LICENSE grants UTMDACC the power to prosecute, and maintain the PATENT RIGHTS. LICENSOR will take reasonable action to require UTTMDACC to prosecute and maintain the PATENT RIGHTS pursuant to the SYSTEM LICENSE. LICENSEE will pay the out-of-pocket costs of searching, preparing, filing, prosecuting and maintaining patents and patent applications within the PATENT RIGHTS in accordance with Section 4.1(a), above. If LICENSEE notifies LICENSOR that it does not intend to pay the cost of filing, prosecuting or maintaining a patent application or patent included in the PATENT RIGHTS, or if LICENSEE fails to promptly confirm its intent to pay the cost of filing, prosecuting or maintaining a patent application or patent included in the PATENT RIGHTS upon inquiry from LICENSOR, or if LICENSEE is in arrears on any expense payments due under Section 4.1(a), then LICENSOR may elect to file, not file, continue prosecution or maintenance, or abandon such patent application or patent at its own expense without further notice to LICENSEE. In the event LICENSOR files or continues prosecution or maintenance of such patent application or patent at its expense, then LICENSEE's rights to such patent application or patent under this AGREEMENT shall terminate in its entirety. With respect to those patent applications for which LICENSEE is paying costs (e.g., costs of preparation, filing and prosecution), LICENSOR will instruct its patent prosecution counsel to: provide LICENSEE with a copy of such patent application and all material documents received or filed during prosecution thereof; and provide copies of all material documents prepared by patent prosecution counsel for submission to governmental patent offices to LICENSEE for review and comment prior to filing, to the extent practicable under the circumstances. LICENSEE may at its own cost, provide comments to LICENSOR as to wording of claims, and responses to office actions prior to their submission to the appropriate patent office. LICENSOR shall consider comments made by LICENSEE regarding prosecution of the PATENT RIGHTS in good faith, but shall not be required to implement them. The parties agree that they share a common legal interest to get valid enforceable patents and that LICENSEE will keep all privileged information received pursuant to this Section confidential. LICENSOR agrees that to the extent UTMDACC controls the filings, prosecution or maintenance of patents and patent applications included in the PATENT RIGHTS, LICENSOR will be responsible for ensuring UTMDACC complies with the provisions of this Section applicable to such patents and patent applications.

VII. INFRINGEMENT BY THIRD PARTIES

7.1 LICENSEE, at its expense, shall have the first option to enforce LICENSOR's rights in any patent exclusively licensed hereunder against infringement by third parties in the LICENSED FIELD and is entitled to retain recovery from such enforcement. After reimbursement of LICENSEE's reasonable legal costs and expenses related to such recovery, LICENSEE agrees to pay LICENSOR 20% of any recovery (whether the award is for lost profits, a reasonable royalty, or another measure of damages). LICENSEE must notify LICENSOR in writing of any potential infringement in the LICENSED FIELD within thirty (30) calendar days of knowledge thereof. If LICENSEE does not file suit against a substantial infringer of an exclusively licensed patent in the LICENSED FIELD (or otherwise cause such substantial infringer to cease all infringing activities to LICENSOR's reasonable satisfaction) within six (6) months of knowledge thereof, then LICENSOR may, at its sole discretion, enforce any patent licensed hereunder on behalf of itself and LICENSEE, with LICENSOR retaining 80% all recoveries from such enforcement and paying 20% to LICENSEE.

7.2 In any suit or dispute involving an infringer pursuant to Section 7.1, the parties agree to cooperate fully with each other. At the request and expense of the party bringing suit, the other party will permit access during regular business hours, to all relevant personnel, records, papers, information, samples, specimens, and the like in its possession.

VIII. PATENT MARKING

8.1 LICENSEE agrees that all packaging containing individual LICENSED PRODUCT(S), documentation therefor, and, when possible, actual LICENSED PRODUCT(S) sold by LICENSEE, AFFILIATES, and/or sublicensees of LICENSEE will be appropriately marked with the number of any applicable patent(s) licensed hereunder in accordance with each country's patent laws, including Title 35, United States Code, to the extent such marking is necessary or required to fully preserve PATENT RIGHTS in each such country.

IX. INDEMNIFICATION, INSURANCE AND REPRESENTATIONS AND WARRANTIES

9.1 LICENSEE agrees to hold harmless and indemnify LICENSOR, its officers, employees, directors and agents from and against any claims, demands, or causes of action whatsoever, costs of suit and reasonable attorney's fees, including without limitation, those arising under the SYSTEM LICENSE and those costs arising on account of any injury or death of persons or damage to property caused by, or arising out of, or resulting from, the exercise or practice of the rights granted hereunder by LICENSEE, its SUBLICENSEES, its AFFILIATES or any of their officers, employees, agents or representatives, provided however that the following is excluded from LICENSEE's obligation to indemnify and hold harmless: (a) the negligent failure of LICENSEE to substantially comply with any applicable governmental requirements; (b) the negligence or willful malfeasance by LICENSEE, its officers, agents, directors or employees; (c) licenses, research agreements, evaluation agreements, material transfer agreements, confidentiality agreements, inter-institutional agreements and other agreements entered into by LICENSOR, the BOARD or UTMDACC that relate to the LICENSED SUBJECT MATTER, PATENT RIGHTS TECHNOLOGY RIGHTS and/or antimicrobial/antiseptic/antibacterial devices, compositions and processes created by Dr. Raad, individually and with others; (d) Great Lakes Pharmaceuticals, Inc; or (e) any breach of its representations warranties or covenants herein.

9.2 LICENSOR agrees to hold harmless and indemnify LICENSEE, its officers, employees, directors and agents from and against any claims, demands, or causes of action whatsoever, costs of suit and reasonable attorney's fees, including without limitation, those costs arising on account of any injury or death of persons or damage to property caused by, or arising out of, or resulting from (i) licenses, research agreements, evaluation and material transfer agreements, material transfer agreements, confidentiality agreements, inter-institutional agreements and other agreements entered into by LICENSOR, the BOARD or UTMDACC that relate to the LICENSED SUBJECT MATTER, PATENT RIGHTS TECHNOLOGY RIGHTS and/or antimicrobial/antiseptic/antibacterial devices, compositions and processes created by Dr. Raad, individually and with others; (ii) Great Lakes Pharmaceuticals, Inc or (iii) any breach of its representations warranties or covenants herein.

9.3 IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR EXPECTED SAVINGS OR OTHER ECONOMIC LOSSES, OR FOR INJURY TO PERSONS OR PROPERTY) ARISING OUT OF, OR IN CONNECTION WITH, THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER EITHER PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING LIMITATION SHALL NOT LIMIT LICENSEE'S OBLIGATIONS UNDER SECTION 9.1 WITH RESPECT TO CLAIMS, DEMANDS AND CAUSES OF ACTION ARISING WITH RESPECT TO THE SYSTEM LICENSE.

9.4 Beginning at the time when any LICENSED SUBJECT MATTER is being distributed or sold for use in or by humans (including for the purpose of obtaining regulatory approvals) by LICENSEE, an AFFILIATE, or by a sublicensee, LICENSEE (directly, or indirectly through a sublicensee) shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than $2,000,000 per incident and $5,000,000 annual aggregate, and LICENSEE shall use reasonable efforts to have the LICENSEE, the Board of Regents of the University of Texas System, the University of Texas System, the University of Texas M. D. Anderson Cancer Center, their Regents, officers, employees, students and agents, named as an additional insured. Such commercial general liability insurance shall provide: (i) product liability coverage; (ii) broad form contractual liability coverage for LICENSEE's indemnification under this AGREEMENT; and (iii) coverage for litigation costs. The minimum amounts of insurance coverage required herein shall not be construed to create a limit of LICENSEE's liability with respect to its indemnification under this AGREEMENT. For clarity, LICENSEE will have been deemed to comply with this Section 9.3 if a sublicensee procures the insurance as described above on behalf of LICENSEE in full compliance with all the provisions of this Section.

9.5 LICENSEE shall provide LICENSOR with written evidence of such insurance within thirty (30) calendar days of its procurement. Additionally, LICENSEE shall provide LICENSOR with written notice of at least fifteen (15) calendar days prior to the cancellation, non-renewal or material change in such insurance.

9.6 LICENSEE shall maintain such commercial general liability insurance beyond the expiration or termination of this AGREEMENT during: (i) the period that any LICENSED SUBJECT MATTER developed pursuant to this AGREEMENT is being commercially distributed or sold by LICENSEE, an AFFILIATE or by a sublicensee or agent of LICENSEE; and (ii) the five (5) year period immediately after such period.

9.7 LICENSOR represents and warrants to LICENSEE that:

(a) it is a limited liability company duly organized and subsisting under the laws of the State of Texas, with the corporate power to own its assets and to carry on its business and has made all necessary filings under all applicable corporate, securities and taxation laws or any other laws to which Licensor is subject;

(b) it has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder;

(c) it has taken all necessary company action on its part required to authorize the execution and delivery of this Agreement;

(d) the entering into and the delivery of this Agreement will not result in the violation of:

(i) any of the provisions of the certificate of organization or operating of the LICENSOR;

(ii) any agreement or other instrument to which the LICENSOR is a party or by which the LICENSOR is bound; or

(iii) any applicable laws, rules or regulations;

(e) this Agreement is a legal and valid obligation binding LICENSOR and is enforceable in accordance with its terms;

(f) it is the owner with full right, power and authority to grant LICENSEE the rights and licenses granted to LICENSEE hereunder in accordance with the terms and conditions of this Agreement;

(g) LICENSOR has not previously licensed, assigned, transferred, or otherwise conveyed any right, title or interest in, to or under the LICENSED SUBJECT MATTER; and the LICENSED SUBJECT MATTER is free and clear of any liens, charges, encumbrances or rights of others to possession or use that would have the effect of preventing LICENSEE from exercising the rights and licenses granted to it hereunder; and

(h) any underlying agreements upon which LICENSOR relies for purposes of granting the rights and licenses to LICENSEE hereunder (true and complete copies of which have been supplied to Company), including the SYSTEM LICENSE AGREEMENT, are in full force and effect in accordance with their terms, and LICENSOR is not in breach thereof or default thereunder.

9.8 LICENSOR shall not amend or waive, or take any other action or commit any omission that would alter or affect, any of its rights under the SYSTEM LICENSE AGREEMENT, in any manner that would materially adversely affect LICENSEE's rights and benefits hereunder or thereunder.

9.9 Except as expressly provided herein, LICENSOR disclaims all other warranties, express or implied, with respect to the LICENSED SUBJECT MATTER or LICENSOR'S rights thereto.

X. USE OF NAME

10.1 LICENSEE will not use the name of (or the name of any employee of) UTMDACC, SYSTEM or BOARD in any advertising, promotional or sales literature, on its Web site, or for the purpose of raising capital without the advance express written consent of BOARD secured through:

The University of Texas
M. D. Anderson Cancer Center
Legal Services, Unit 1674
P.O. Box 301407
Houston, TX 77230-1407
ATTENTION: [*]
Email: [*]

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

Notwithstanding the above, LICENSEE may use the name of (or name of employee of) UTMDACC, SYSTEM or BOARD in routine business correspondence, or as needed in appropriate regulatory submissions without express written consent.

XI. CONFIDENTIAL INFORMATION AND PUBLICATION

11.1 LICENSOR and LICENSEE each agree that information disclosed in connection with an examination under Section 4.3 and all information contained in documents marked "confidential" and forwarded to one by the other (i) are to be received in strict confidence, (ii) are to be used only for the purposes of this AGREEMENT, and (iii) will not be disclosed by the recipient party (except as required by law or court order), its agents or employees without the prior written consent of the disclosing party, except to the extent that the recipient party can establish by competent written proof that such information:

(a) was in the public domain at the time of disclosure; or

(b) later became part of the public domain through no act or omission of the recipient party, its employees, agents, successors or assigns; or

(c) was lawfully disclosed to the recipient party by a third party having the right to disclose it; or

(d) was already known by the recipient party at the time of disclosure; or

(e) was independently developed by the recipient party without use of the disclosing party's confidential information; or

(f) is required by law or regulation to be disclosed.

11.2 Each party's obligation of confidence hereunder will be fulfilled by using at least the same degree of care with the disclosing party's confidential information as it uses to protect its own confidential information, but always at least a reasonable degree of care. This obligation will exist while this AGREEMENT is in force and for a period of five (5) years thereafter.

11.3 LICENSEE may disclose confidential information of LICENSOR, BOARD and/or UTMDACC to its sublicensees and potential sublicensees in accordance with Section 11.2, provided such recipient agrees in writing to keep such information confidential under obligations equivalent to or stricter than those agreed to by LICENSEE hereunder. The terms of this AGREEMENT (other than the identity of the parties and the LICENSED FIELD) shall be treated as confidential information of all parties, provided that LICENSEE may disclose the terms of this AGREEMENT to prospective sources of financing, investors, lenders, investment bankers and potential SUBLICENSEEs. Either party may disclose identity of the parties and the LICENSED FIELD to third parties.

XII. ASSIGNMENT

12.1 Except in connection with a merger or the sale or transfer of substantially all of LICENSEE's assets relating to this Agreement to a third party, this AGREEMENT may not be assigned by LICENSEE, in whole or in part, without the prior written consent of LICENSOR, which consent will not be unreasonably withheld or delayed. For any assignment to be effective: (a) the LICENSEE must timely pay LICENSOR the Assignment Fee specified in Section 4.1; and (b) the assignee must assume in writing (a copy of which writing will be provided to LICENSOR) all of LICENSEE's interests, rights, duties, and obligations under the AGREEMENT and agree to comply with all terms and conditions of the AGREEMENT as if the assignee were the original party (i.e., the LICENSEE) to the AGREEMENT.

XIII. TERM AND TERMINATION

13.1 Subject to Sections 13.2, 13.3 and 13.4 hereinbelow, the term of this AGREEMENT is from the EFFECTIVE DATE until the ROYALTY EXPIRATION DATE. LICENSEE shall have no obligation under this AGREEMENT to pay royalties for NET SALES of LICENSED PRODUCTS occurring after the ROYALTY EXPIRATION DATE.

13.2 LICENSOR shall have the right to terminate this AGREEMENT in its entirety upon thirty (30) calendar days prior written notice from LICENSOR to LICENSEE, if LICENSEE fails to achieve each of the following diligence milestones and provide evidence, reasonably satisfactory to LICENSOR, that each such milestone has been achieved by the due date:

(a) First SALE of a LICENSED PRODUCT on or before the earlier of (i) five years from the Effective Date or (ii) two years following receipt of the final report from a Pivotal Trial. “Pivotal Trial” means a human clinical trial intended to provide the substantial evidence of efficacy necessary to support the filing of n approvable NDA or PMA with the FDA;

(b) Initiation of a Pivotal Trial for a LICENSED PRODUCT within 18 months following LICENSEE’s receipt of the final report from the first human clinical trial conducted by LICENSEE involving the Licensed Product;

(c) LICENSEE shall raise $7.5 Million in COMPANY FUNDING on or before the third anniversary of the EFFECTIVE DATE; and

(d) During each of the three years of the Agreement following the Effective Date, the cumulative direct and indirect costs and expenses (including overhead) incurred by LICENSEE and its AFFILIATES AND SUBLICENSEES on the research, development, manufacture and commercialization of Licensed Products will, equal or exceed the following amounts: (i) year 1: $2,500,000, (ii) year 2, $1,000,000 and (iii) year 3, $1,000,000.

As used in this Section 13.3, "COMPANY FUNDING" shall be calculated by adding together the following amounts: (1) one hundred percent (100%) of cash actually received by LICENSEE from investors to purchase an equity or ownership interest in LICENSEE; (2) fifty percent (50%) of grant money and/or research and development funds actually received by LICENSEE from a governmental body or independent third party, provided that such funds are required to be spent by or on behalf of LICENSEE for future research and development of a LICENSED PRODUCT; (3) one hundred percent (100%) of research and development funds actually received by LICENSEE from a sublicensee, provided that such funds are required to be spent by or on behalf of LICENSEE for future research and development of a LICENSED PRODUCT; and (4) 100% of royalties received by LICENSEE from a sublicensee from the SALE of a LICENSED PRODUCT less any royalty owed to LICENSOR pursuant to Section 4.1(d) and Section 4.1(i).

13.4 Subject to any rights herein which survive termination, this AGREEMENT will earlier terminate in its entirety:

(a) automatically, if LICENSEE becomes bankrupt or insolvent and/or if the business of LICENSEE shall be placed in the hands of a receiver, assignee, or trustee, whether by voluntary act of LICENSEE or otherwise; or

(b) upon forty-five (45) calendar days written notice from LICENSOR, if LICENSEE breaches or defaults on the payment or report obligations of ARTICLE IV (excluding the license documentation fee specified in Section 4.1(b), for which no cure period applies), or use of name obligations of ARTICLE X, unless, before the end of such forty-five (45)-calendar day notice period, LICENSEE has cured the default or breach to LICENSOR's reasonable satisfaction, and so notifies LICENSOR, stating the manner of the cure; or

(c) upon ninety (90) calendar days written notice from LICENSOR if LICENSEE breaches or defaults on any other obligation under this AGREEMENT, unless, before the end of such ninety (90) calendar-day notice period, LICENSEE has cured the default or breach to LICENSOR's reasonable satisfaction and so notifies LICENSOR, stating the manner of the cure; or

(d) at any time by mutual written agreement between LICENSEE and LICENSOR upon one hundred eighty (180) calendar days written notice to all parties and subject to any terms herein which survive termination; or

(e) As set forth in Sections 13.3 and 15.9; or

(f) immediately, upon written notice from LICENSOR, if LICENSEE has defaulted or been late on its payment obligations pursuant to the terms of this AGREEMENT on any three (3) occasions in an eighteen (18) month period; or

(g) immediately, upon written notice from LICENSOR, if LICENSEE fails to timely pay the license fee specified in Section 4.1(b); or

(h) without cause, by LICENSEE, upon one hundred eighty (180) calendar days written notice from LICENSEE to LICENSOR; or

13.5 Upon termination of this AGREEMENT:

(a) nothing herein will be construed to release either party of any obligation maturing prior to the effective date of the termination; and

(b) The provisions of ARTICLES IX (Indemnification and Insurance), X (Use of Name) and XI (Confidential Information and Publication) shall survive termination of this AGREEMENT; and

(c) LICENSEE may, for a period of one year after the effective date of the termination of this AGREEMENT in its entirety, sell all LICENSED PRODUCTS and parts therefor that it has on hand at the date of termination, if LICENSEE pays the earned royalty thereon and any other amounts due pursuant to ARTICLE IV of this AGREEMENT; and

(d) Subject to Section 13.5(c), LICENSEE agrees to cease and desist any use and all SALE of the LICENSED SUBJECT MATTER and LICENSED PRODUCTS upon termination of this AGREEMENT.

XIV. SUPERIOR RIGHTS

14.1 LICENSEE understands that the LICENSED SUBJECT MATTER may have been developed under a funding agreement with the Government of the United States of America ("Government") and, if so, that the Government may have certain rights relative thereto. This AGREEMENT is explicitly made subject to the Government's rights under any such agreement and any applicable law or regulation. To the extent that there is a conflict between any such agreement, applicable law or regulation and this AGREEMENT, the terms of such Government agreement, applicable law or regulation shall prevail. To the extent the LICENSED SUBJECT MATTER was developed under a funding agreement with the Government, LICENSEE shall comply with the requirements of such funding agreement and any applicable law or regulation, including any requirements for United States manufacture. Accordingly, LICENSEE agrees that any LICENSED PRODUCTS developed under a funding agreement with the Government will be manufactured substantially in the United States, to the full extent required under applicable law and regulations, unless a written waiver is obtained in advance from the GOVERNMENT. LICENSEE will promptly advise LICENSOR if such a written waiver is requested and/or obtained.

14.2 LICENSEE understands, acknowledges and agrees that LICENSOR, by this AGREEMENT, makes no representation as to the operability or fitness for any use, safety, efficacy, approvability by regulatory authorities, time and cost of development, patentability, and/or breadth of the LICENSED SUBJECT MATTER. LICENSOR, by this AGREEMENT, also makes no representation as to whether any patent covered by PATENT RIGHTS is valid or as to whether there are any patents now held, or which will be held, by others or by, LICENSOR, SYSTEM or UTMDACC in the LICENSED FIELD, nor does LICENSOR make any representation that the inventions contained in PATENT RIGHTS do not infringe any other patents now held or that will be held by others or by LICENSOR, UTMDACC OR SYSTEM.

XV. GENERAL

15.1 This AGREEMENT constitutes the entire and only agreement between the parties for LICENSED SUBJECT MATTER and all other prior negotiations, representations, agreements and understandings are superseded hereby. No agreements altering or supplementing the terms hereof will be made except by a written document signed by both parties.

15.2 Any notice required by this AGREEMENT must be given by prepaid, first class, certified mail, return receipt requested, or by overnight delivery by a nationally recognized delivery service with signature proof of delivery, and addressed in the case of LICENSOR to:

Novel Anti-Infective Technologies, LLC
4207 Clearwater Ct.
Missouri City, TX 77459
ATTENTION: David McWilliams

or in the case of LICENSEE to:

Leonard Meron Biosciences, Inc.
11 Commerce Drive, First Floor
Cranford, NJ 07016
ATTENTION: Myron Holubiak, CEO

or such other addresses as may be given from time to time under the terms of this notice provision.

15.3 LICENSEE must comply with all applicable federal, state and local laws and regulations in connection with its activities pursuant to this AGREEMENT. LICENSEE acknowledges that the LICENSED SUBJECT MATTER is subject to U. S. export control jurisdiction. LICENSEE agrees to comply with all applicable international and national laws that apply to the LICENSED SUBJECT MATTER, including U.S. Export Administration Regulations, as well as end-user, end-use, and destination restrictions applied by the United States.

15.4 This AGREEMENT will be construed and enforced in accordance with the laws of the United States of America and of the State of Texas, without regard to its conflict of law provisions. The Texas State Courts of Harris County, Texas (or, if there is exclusive federal jurisdiction, the United States District Court for the Southern District of Texas) shall have exclusive jurisdiction and venue over any dispute arising out of this AGREEMENT, and LICENSEE consents to the jurisdiction and venue of such courts. Nothing in this AGREEMENT shall be deemed as a waiver by BOARD, SYSTEM or UTMDACC of its sovereign immunity.

15.5 Omitted.

15.6 Failure of LICENSOR or LICENSEE to enforce a right under this AGREEMENT will not act as a waiver of right or the ability to later assert that right relative to the particular situation involved.

15.7 Headings included herein are for convenience only and will not be used to construe this AGREEMENT.

15.8 If any part of this AGREEMENT is for any reason found to be unenforceable, all other parts nevertheless will remain enforceable.

15.9 In the event that LICENSEE brings an action before any court, agency or tribunal seeking to invalidate or otherwise challenge the enforceability of or BOARD's ownership of any patent included in the PATENT RIGHTS, then LICENSOR may immediately terminate this AGREEMENT upon written notice to LICENSEE. Any such dispute regarding the validity, enforceability or ownership of any patent included in the PATENT RIGHTS shall be litigated in the courts located in Houston, Texas, and LICENSEE agrees not to challenge personal jurisdiction in that forum. To the extent that LICENSEE unsuccessfully challenges the validity or enforceability of any patent included in the PATENT RIGHTS, LICENSEE agrees to reimburse UTMDACC and BOARD for all costs and fees (including attorney's fees) paid by UTMDACC and BOARD in defending against such challenge. LICENSEE understands and agrees that, in the event LICENSEE successfully challenges the validity or enforceability of any patent included in the PATENT RIGHTS, all payments or other consideration made or otherwise provided by LICENSEE to LICENSOR prior to a final, non-appealable adjudication of invalidity and/or unenforceability shall be non-refundable. The obligations of this Section shall survive the expiration or termination of this AGREEMENT.

15.10 This AGREEMENT may be executed by the parties in counterparts (each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement) and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other party. All signatures need not be on the same counterpart page.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this PATENT AND TECHNOLOGY LICENSE AGREEMENT.

LEONARD-MERON BIOSCIENCES, INC.

By /s/ Myron Holubiak
Printed Name: Myron Holubiak
Title: Chief Executive Officer

NOVEL ANTI-INFECTIVE TECHNOLOGIES, LLC

By /s/ David B. McWilliams
Printed Name: David B. McWilliams
Title: Chairman

EXHIBIT 1

PART A -SALVAGE

MDA No. (each an individual technology)	Inventors	IDR Title	U.S. and foreign patent application/patent numbers
MDA03-038	Issam I Raad, M.D.	Antimicrobials in Combination with Chelators and Ethanol for the Rapid Eradication of Microorganisms Embedded in Biofilm	U.S. Patent No.: 7,601,731; EP Serial No.: 04754538.9; CA Serial No.: 2,528,522; U.S. Serial No.: 13/095,262; U.S. Serial No.: 13/621,628

EXHIBIT 2

MDA03-038: "Licensed Field" means the medical use of compositions comprising tetracycline, a chelator, and an alcohol as a salvage catheter lock/flush (i.e. not maintenance catheter lock/flush) solution in indwelling catheters, provided that such composition does not contain any antibiotics or other antimicrobials other than one or more tetracyclines. As used in this AGREEMENT, "tetracycline" means minocycline, tigecycline, doxycycline, demeclocycline, anhydrotetracycline, chlorotetracycline, or epioxytetracycline or equivalent drug in the tetracycline class. Notwithstanding the foregoing, the Licensed Field shall not include the Excluded Fields, set forth below.

Excluded Fields:

The Licensed Field(s) of use set forth above shall not include any of the "Excluded Fields." As used herein, "Excluded Fields" means the following:

(1) the coating of catheters in combination with antibiotics or other antimicrobials and the resultant catheters, including, but not limited to, any use of an antibiotic or other antimicrobial that creates a coating on or otherwise coats a catheter with an antibiotic or other antimicrobial;

(2) Antimicrobial gloves, including but not limited to: antimicrobial medical gloves for examination and/or surgical applications; and antimicrobial gloves for industrial and/or food-service applications; and

(3) cardiac pacemakers, cardiac defibrillators, cardiac pacemaker leads; and cardiac defibrillator leads, (collectively, "Cardiac Devices") which either may be coated with antimicrobial agents or placed into or covered by a receptacle, mesh, envelope, pouch, sleeve, sheath, boot, jacket or other cover (collectively "Pouch(es)") coated with antimicrobial agents; (b) surgical site repair mesh, including but not limited to hernia repair mesh and incisional wound closure mesh, in each case coated with antimicrobial agents, (c) Pouches into which one or more of the following devices are placed, in whole or in part: implantable infusion devices (i.e. drug pumps) (including leads, adapters and extensions for such devices); and (d) pulse generators (i.e., non-cardiac and vagus nerve stimulators) (including leads, adapters and extensions for such devices) which either may be coated with antimicrobial agents or placed into Pouch(es).

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Myron Holubiak, certify that:

1. I have reviewed this report on Form 10-Q of Citius Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 14, 2019

By: */s/ Myron Holubiak*
Myron Holubiak
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002

I, Jaime Bartushak, certify that:

1. I have reviewed this report on Form 10-Q of Citius Pharmaceuticals, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 14, 2019

By: */s/ Jaime Bartushak*
Jaime Bartushak
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
AND THE CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Citius Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Myron Holubiak, Chief Executive Officer of the Company, and Jaime Bartushak, Chief Financial Officer of the Company certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) 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.

Date: February 14, 2019

By: */s/ Myron Holubiak*
Myron Holubiak
Chief Executive Officer,
(Principal Executive Officer)

Date: February 14, 2019

By: */s/ Jaime Bartushak*
Jaime Bartushak
Chief Financial Officer
(Principal Financial and Accounting Officer)