# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2019

□ 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 001-13467

# Inhibitor Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

4830 W. Kennedy Blvd., Suite 600 Tampa, FL (Address of principal executive offices) 30-0793665 (I.R.S. Employer Identification No.)

> 33609 (Zip Code)

Registrant's telephone number (including area code): 813-509-2417

Not Applicable

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

#### Securities registered pursuant to Section 12(b) of the Act: None

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T ( $\S232.405$  of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  $\boxtimes$  No  $\square$ 

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

Large accelerated filer	Accelerated filer	
Non-accelerated filer	Smaller reporting company	X
	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 November 6, 2019, there were 370,446,185 shares of company common stock issued and outstanding.

### Inhibitor Therapeutics, Inc.

#### Quarterly Report on Form 10-Q

# TABLE OF CONTENTS

1

2

3

4

5

12

13

13

14

15

15

15

15

15

15

16

#### Page Part I. Financial Information Item 1. Condensed Financial Statements (unaudited) Condensed Balance Sheets as of September 30, 2019 and December 31, 2018 Condensed Statements of Operations for the three months and nine months ended September 30, 2019 and 2018 Condensed Statement of Stockholders' Equity (Deficit) for the nine months ended September 30, 2019 and 2018 Condensed Statements of Cash Flows for the nine months ended September 30, 2019 and 2018 Notes to Condensed Financial Statements Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosures about Market Risk Item 3. Item 4. Controls and Procedures Cautionary Note on Forward Looking Statements Part II. Other Information Legal Proceedings Item 1 Item 1A. **Risk Factors** Item 2 Unregistered Sales of Equity Securities and Use of Proceeds Defaults upon Senior Securities Item 3 Item 4 Mine Safety Disclosures Item 5 Other Information **Exhibits** Item 6. **Signatures** S-1

# INHIBITOR THERAPEUTICS, INC. CONDENSED BALANCE SHEETS AS OF SEPTEMBER 30, 2019 AND DECEMBER 31, 2018 (Unaudited)

		ember 30, 2019	December 31, 2018	
ASSETS				
Current assets:				
Cash and cash equivalents	\$	1,372,186	\$	1,108,713
Prepaid expenses		50,660		41,296
Total current assets		1,422,846		1,150,009
Other long-term assets		61,023		82,992
Total assets	\$	1,483,869	\$	1,233,001
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
Current liabilities:				
Accounts payable	\$	285,982	\$	384,829
Dividends payable		50,410		99,945
Other liabilities		22,533		215,876
Total current liabilities		358,925		700,650
Deferred revenue, related party		3,000,000		500,000
Total liabilities		3,358,925		1,200,650
Commitments and contingencies (note 5)				
Stockholders' (deficit) equity:				
Series A Preferred Stock, \$0.0001 par value; 500,000 shares authorized; no shares issued and				
outstanding		—		—
Series B Convertible, Redeemable, Preferred Stock, \$0.0001 par value; 7,246,377 shares				
authorized; 5,797,102 shares issued and outstanding at September 30, 2019 and December 31,		2.000.000		2.000.000
		3,960,866		3,960,866
Undesignated Preferred Stock, \$0.0001 par value; 2,253,623 shares authorized; no shares issued or outstanding		_		_
Common stock, \$0.0001 par value; 500,000,000 shares authorized; 370,446,185 and 370,084,064				
shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively		37,045		37,008
Additional paid-in capital		49,354,791		49,015,120
Accumulated deficit		(55,227,758)		(52,980,643)
Total stockholders' (deficit) equity		(1,875,056)		32,351
Total liabilities and stockholders' (deficit) equity	\$	1,483,869	\$	1,233,001

See notes to condensed financial statements

#### INHIBITOR THERAPEUTICS, INC. CONDENSED STATEMENTS OF OPERATIONS FOR THE THREE MONTH AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2019 AND 2018 (Unaudited)

	Three Months Ended September 30,			Nine Months Ended September 30			ember 30,	
	2019		2018		2019		2018	
Revenues:	\$	_	\$		\$ -	_	\$	
Expenses:								
Research and development		364,442		775,449	864,8	312		1,978,294
General and administrative		318,479		400,076	1,245,2	209		1,256,453
Total Expenses:		682,921		1,175,525	2,110,0	)21	3	3,234,747
Loss from operations		(682,921)		(1,175,525)	(2,110,0	)21)	(3	3,234,747)
Interest income		4,373		3,995	12,4	194		10,707
Net loss	\$	(678,548)	\$	(1,171,530)	(2,097,5	527)	(3	3,224,040)
Preferred stock dividend		(50,410)		(49,534)	(149,5	588)		(106,082)
Net loss applicable to common stockholders	\$	(728,958)	\$	(1,221,064)	\$ (2,247,	115)	<u>\$</u> (3	3,330,122)
Basic and diluted net loss applicable to common stockholders per share	\$	(0.00)	\$	(0.00)	\$ (0	.01)	\$	(0.01)
Weighted average common stock shares outstanding - basic and diluted		70,446,185		369,930,943	370,427,0	515	369	9,757,743

See notes to condensed financial statements

#### INHIBITOR THERAPEUTICS, INC. CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018 (Unaudited)

	Preferred Stock – Series B		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity	
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)	
Balances, January 1, 2019	5,797,102	\$3,960,866	370,084,064	\$37,008	\$49,015,120	\$(52,980,643)	\$ 32,351	
Issuance of common stock for payment of dividends on								
Preferred Stock			362,121	37	99,909		99,946	
Stock based compensation	—			—	131,031		131,031	
Preferred stock dividends	—	_	_	_	_	(49,315)	(49,315)	
Net loss	—			—		(786,288)	(786,288)	
Balances, March 31, 2019	5,797,102	\$3,960,866	370,446,185	\$37,045	\$49,246,060	\$(53,816,246)	\$ (572,275)	
Stock based compensation	—			—	81,614	_	81,614	
Preferred stock dividends	—	_	_	_	_	(49,863)	(49,863)	
Net loss						(632,691)	(632,691)	
Balances, June 30, 2019	5,797,102	\$3,960,866	370,446,185	\$37,045	\$49,327,674	\$(54,498,800)	\$(1,173,215)	
Stock based compensation	—			_	27,117	_	27,117	
Preferred stock dividends	_			_		(50,410)	(50,410)	
Net loss						(678,548)	(678,548)	
Balances, September 30, 2019	5,797,102	\$3,960,866	370,446,185	\$37,045	\$49,354,791	(55,227,758)	(1,875,056)	

	Mezzanine Equity Preferred Stock–Series B		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity	
	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)	
Balances, January 1, 2018		\$ —	369,599,266	\$36,960	\$48,403,523	\$(48,273,920)	\$ 166,563	
Sale of Preferred Stock and Common Stock warrants								
to related party, net (note 1)	3,478,261	2,360,866		—		_	_	
Stock based compensation	—	—	75,000	7	208,236	—	208,243	
Preferred stock dividends						(26,630)	(26,630)	
Net loss						(1,170,594)	(1,170,594)	
Balances, March 31, 2018	3,478,261	2,360,866	369,674,266	\$36,967	\$48,611,759	\$(49,471,144)	\$ (822,418)	
Issuance of common stock upon warrant exercise			100,000	10	11,990		12,000	
Stock based compensation	—			—	83,953	—	83,953	
Preferred stock dividends				—	—	(29,918)	(29,918)	
Net loss						(881,916)	(881,916)	
Balances, June 30, 2018	3,478,261	2,360,866	369,774,266	36,977	48,707,702	(50,382,978)	(1,638,299)	
Sale of Preferred Stock and Common Stock warrants								
to related party, net (note 1)	2,318,841	1,600,000		_			—	
Stock based compensation		_		—	125,451		125,451	
Issuance of common stock for payment of dividends								
on Preferred Stock	_	_	184,798	19	56,529	_	56,548	
Preferred stock dividends	_	—		—		(49,534)	(49,534)	
Net loss						(1,171,530)	(1,171,530)	
Balances, September 30, 2018	5,797,102	\$3,960,866	369,959,064	\$36,996	\$48,889,682	\$(51,604,042)	\$(2,677,364)	

See notes to condensed financial statements

#### INHIBITOR THERAPEUTICS, INC. CONDENSED STATEMENTS OF CASH FLOWS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018 (Unaudited)

	Nine Months Ended September 30,	
	2019	2018
Operating activities:		
Net loss	\$(2,097,527)	\$(3,224,040)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	239,762	417,647
Changes in assets and liabilities:		
Prepaid expense and other assets	12,605	32,183
Accounts payable and other current liabilities	(292,189)	(101,943)
Net cash used in operating activities	(2,137,349)	(2,876,153)
Financing activities:		
Proceeds from the exercise of common stock warrants	—	12,000
Proceeds from the sale of preferred stock and common stock warrants, related party, net (note 1)	—	3,960,866
Proceeds from advances of royalties, related party	2,500,000	_
Payment of cash dividend	(99,178)	
Net cash provided by financing activities	2,400,822	3,972,866
Net change in cash and cash equivalents	263,473	1,096,713
Cash and cash equivalents at beginning of period	1,108,713	344,113
Cash and cash equivalents at end of period	\$ 1,372,186	<u>\$ 1,440,826</u>
Non-cash financing activities:		
Issuance of common stock for payment of Preferred Stock dividend	<u>\$ 99,946</u>	<u>\$ 56,548</u>
Accrued, but unpaid dividends	\$ 50,410	\$ 49,534

See notes to condensed financial statements

#### 1. Corporate overview:

#### Overview

The accompanying unaudited condensed financial statements of Inhibitor Therapeutics, Inc. (formerly HedgePath Pharmaceuticals, Inc.), a Delaware corporation (the "Company", "INTI", "we", "us" or similar terminology), have been prepared by the Company without audit. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position, results of operations and cash flows as of September 30, 2019, and for all periods presented, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") have been condensed or omitted pursuant to the Securities and Exchange Commission ("SEC") rules and regulations. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2018, which are included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, which was filed with the SEC on March 7, 2019 (the "2018 Annual Report"). The accompanying condensed balance sheet as of December 31, 2018 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements.

As used herein, the term "Common Stock" means the Company's common stock, \$0.0001 par value per share.

The results of operations for the three and nine month periods ended September 30, 2019 are not necessarily indicative of results that may be expected for any other interim period or for the full fiscal year. Readers of this Quarterly Report are strongly encouraged to review the risk factors relating to the Company which are set forth in the 2018 Annual Report and our other filings with the SEC.

#### Nature of the Business and Background

The Company is a pharmaceutical development company that is focused on developing and ultimately commercializing innovative therapeutics for patients with certain cancers and certain non-cancerous proliferation disorders. The Company has also explored and expects to continue to explore acquiring or licensing other innovative preclinical and clinical stage therapeutics addressing unmet needs and orphan indications beyond cancer. The Company's current primary focus is on the development of therapies initially for prostate and also lung cancers in the U.S. market utilizing SUBA®-Itraconazole, a patented, oral formulation of the currently marketed anti-fungal drug itraconazole to which the Company holds an exclusive U.S. license in the licensed field from its majority stockholder, Mayne Pharma Ventures Pty Ltd. ("Mayne Pharma"). SUBA-Itraconazole is currently licensed to the Company by Mayne Pharma on an exclusive basis in the United States in the field of certain cancers (including prostate and lung cancer) and certain non-cancerous proliferation disorders pursuant to the Third Amended SLA"). Previously, the Company conducted a Phase 2b trial studying the use of SUBA-Itraconazole targeting basal cell carcinoma in patients with Basal Cell Carcinoma Nevus Syndrome ("BCCNS"). As described further below, Mayne Pharma assumed control of the Company's clinical and regulatory program for SUBA-Itraconazole for the treatment of BCCNS in December 2018 pursuant to the Third Amended SLA.

The Company demonstrated in its previous Phase 2b trial in BCCNS that the dosing of oral capsules of SUBA-Itraconazole affects the Hedgehog signaling pathway, a major regulator of many fundamental cellular processes, which, in turn, can impact the development and growth of cancers such as basal cell carcinoma. Itraconazole has been approved by the U.S. Food and Drug Administration ("FDA") for, and has been extensively used to, treat fungal infections and has an extensive history of safe and effective use in humans. The Company has developed, optioned and licensed intellectual property and know-how related to the treatment of cancer patients using itraconazole and certain itraconazole analogues.

#### Manufacturing and Product Supply Relationship with Mayne Pharma

The Company does not have any production facilities or manufacturing personnel. The Third Amended SLA provides for the supply to the Company of specially formulated capsules of SUBA-Itraconazole, manufactured by Mayne Pharma under cGMP (current good manufacturing practice) standards, for use by the Company in its clinical trials and for the future commercial supply following FDA approvals, if obtained.

Pursuant to the Third Amended SLA, Mayne Pharma is obligated to supply the Company with its patented formulation of SUBA-Itraconazole in a particular oral dose formulation for the treatment of human patients with certain cancers and non-cancerous proliferation disorders for as long as the Third Amended SLA is in effect. The Company is required to perform specified development activities and to commercialize SUBA-Itraconazole for the treatment of cancer in the United States.

#### 1. Corporate overview (continued):

Overview of December 2018 Transactions with Mayne Pharma

On December 17, 2018 (the "Effective Date"), the Company entered into the following related agreements (collectively, the "Transaction Documents"):

- An agreement (the "Agreement"), by and among the Company, and Mayne Pharma, and Mayne Pharma International Pty Ltd, an affiliate of Mayne Pharma ("Mayne Pharma International");
- The Third Amended SLA, which amended and restated the Company's Second Amended and Restated Supply and License Agreement
  with Mayne Pharma, dated as of May 15, 2015 (as amended immediately prior to the Effective Date, the "Second Amended SLA");
  and
- The Amended and Restated Sublicense Agreement, by and between the Company and Mayne Pharma International, which amends and
  restates that certain Sublicense Agreement, dated August 31, 2015, between the Company and Mayne Pharma International, as
  amended.

In addition, pursuant to the terms of the Agreement, the Company and Mayne Pharma agreed to vote in favor of the adoption of an Amended and Restated Certificate of Designation (the "Amended and Restated COD") for the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock"), which amended and restated the terms of the Series B Preferred Stock (originally issued to Mayne Pharma on January 8, 2018) to remove the redemption rights of the Series B Preferred Stock as described below. At September 30, 2019, all 5,797,102 outstanding shares the Series B Preferred Stock are held by Mayne Pharma.

The Transaction Documents resulted from negotiations regarding the existing right of Mayne Pharma under the Second Amended SLA to elect to assume control of the regulatory and clinical development program for SUBA-Itraconazole for the treatment of BCCNS (such product candidate "SUBA-Itraconazole BCCNS") in exchange for a royalty on any future net sales of SUBA-Itraconazole BCCNS by Mayne Pharma in the United States if an FDA New Drug Application ("NDA") was not accepted for filing by FDA by December 31, 2018 (subject to limited extension if the NDA were filed in December 2018). Based on unforeseen requirements imposed by FDA in September 2018, the Company determined that it would be unable to responsibly file the SUBA-Itraconazole BCCNS NDA by this deadline, and thus the Company commenced negotiations with Mayne Pharma to transfer SUBA-Itraconazole BCCNS in advance of December 31, 2018 on negotiated terms deemed beneficial to the Company.

The Transaction Documents were negotiated and approved on behalf of the Company by a special committee of disinterested, independent members of the Company's Board of Directors (the "Board") which was formed on October 26, 2018 for such purpose. The special Board committee consisted of three members of the Board who were each disinterested with respect to Mayne Pharma.

#### December 2018 Agreement with Mayne Pharma

Pursuant to the terms of the Agreement, on the Effective Date, Mayne Pharma (in its capacity as the holder of more than 50% of the outstanding voting securities of the Company) executed and delivered to the Company a stockholder consent which consented to the taking of the following actions: (a) the adoption of the Amended and Restated COD; (b) the election of each E. Brendan Magrab, W. Mark Watson, Dr. R. Dana Ono, Stefan J. Cross and Robert D. Martin (each a current member of the Board, except Brendan Magrab, who resigned effective June 30, 2019) to serve on the Board for a one-year term that expires at the next annual meeting of the Company's stockholders or until his earlier death, resignation or removal; and (c) the approval of an increase in the size of the Company's 2014 Equity Incentive Plan (as amended, the "EIP") by 11,000,000 shares of common stock from 32,583,475 shares.

In addition, pursuant to the Agreement, for the period beginning on the Effective Date and ending three (3) years from the Effective Date, in the event that the Company asks its stockholders (whether at a meeting of stockholders or pursuant to a written consent of stockholders) to vote on or approve a proposal to effect a reverse split of the Company capital stock for the purpose of uplisting the common stock to a U.S. national securities exchange (a "Reverse Stock Split Proposal"), Mayne Pharma (on behalf of itself and its affiliates) agreed to vote or cause to be voted (in person, by proxy or by action by written consent, as applicable) all shares of the Company's voting capital stock that either Mayne Pharma then owns or over which Mayne Pharma has voting control in favor of the adoption and approval of any such Reverse Stock Split Proposal. No assurances are given that the Company will seek an uplisting to a U.S. national securities exchange or implement a reverse stock split of its Common Stock.

#### 1. Corporate overview (continued):

Also, pursuant to the Agreement, Mayne Pharma consented and agreed (under the terms of agreements previously executed with the Company) to an increase in the number of shares of common stock that the Company may issue under the EIP to 17,624,000 shares from the previous limit of 6,624,000 shares, with the agreement and understanding that such increase will be utilized by the Company during the period from the Effective Date through December 31, 2021.

#### December 2018—Third Amended and Restated Supply and License Agreement with Mayne Pharma

Pursuant to the Third Amended SLA, as of the Effective Date, Mayne Pharma assumed control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS and immediately assumed responsibility for all expenses related to exploiting the SUBA-Itraconazole product in the BCCNS field, provided that the Company continues to be responsible for all liabilities related to the product in the United States prior to the Effective Date. The Third Amended SLA will continue in effect on an exclusive basis in the United States on substantially the same terms as were provided for under the Second Amended SLA, except as described below.

In consideration of the transfer to Mayne Pharma of the SUBA-Itraconazole BCCNS clinical data and regulatory rights, the Company will receive the following consideration:

- (a) a 9% quarterly cash royalty (the "Royalty") on future net sales, if any, of SUBA-Itraconazole product in the BCCNS field in the United States, from which certain royalties owed by the Company to Mayne Pharma for access to certain patents would also be funded.
- (b) Mayne Pharma's agreement to advance funds to the Company in an aggregate amount of up to \$5 million on the following terms and conditions:
  - As of the Effective Date, Mayne Pharma shall make an Advance to the Company of \$500,000 (the Company received this first Advance on December 18, 2018);
  - Within three (3) business days following the completion of the agreed upon activities associated with transferring the SUBA-Itraconazole BCCNS product to Mayne Pharma, Mayne Pharma must make an Advance to the Company of \$1 million (the Company received this second Advance on January 22, 2019);
  - (iii) If, and only if, the Company's Phase 2b clinical trial data have been provided to Mayne Pharma in all material respects so as to allow Mayne Pharma to assume control of SUBA-Itraconazole BCCNS in the United States, upon the earlier of June 30, 2019 or the acceptance for filing by FDA of an NDA for the SUBA-Itraconazole BCCNS, Mayne Pharma must make an Advance to the Company of \$1,500,000 (the Company received this third Advance on June 26, 2019); and
  - (iv) If the Company raises aggregate gross proceeds of more than \$3 million from the sale of new common stock, preferred stock equity subordinate to the Series B Preferred Stock held by Mayne Pharma or warrants to third parties ("New Securities") in one or more equity financings by June 30, 2021 (the "Equity Funding Achievement"), the Company may request additional Advances of up to an amount equal to \$2 million less the amount of aggregate gross proceeds received by the Company from Mayne Pharma from the sale of New Securities if Mayne Pharma elects to participate in such equity financings pursuant to contractual pro rata participation rights contained in the Third Amended SLA.
- (c) The field covered by the Third Amended SLA was amended to specifically include only the following indications: (i) any prostate cancer, prostatic intraepithelial neoplasia and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia, and (iii) familial adenomatous polyposis, colorectal polyps and Barett's esophagus (the "Field"). The Company's work on these indications will no longer be tied to the achievement of clinical or commercial target dates as they were under the Second Amended SLA.

#### 1. Corporate overview (continued):

- (d) Mayne Pharma will continue to provide quantities of SUBA-Itraconazole drug and placebo oral capsules without charge up to a contractually set amount for the Company's SUBA-Itraconazole Prostate clinical studies and quantities for future indications as agreed to by the parties.
- (e) Pursuant to the Third Amended SLA, Mayne Pharma has licensed to the Company the right to use all pre-clinical or clinical trial or other data generated or owned by Mayne Pharma related to SUBA-Itraconazole anywhere in the world for its activities under the Third Amended SLA.

With respect to each Advance made by Mayne Pharma prior to the receipt of FDA approval of an NDA for SUBA-Itraconazole BCCNS, each \$0.75 increment of each such Advance will be credited and set off against each \$1.00 increment of Royalty owed to the Company, and with respect to each Advance made by Mayne Pharma following the receipt of FDA approval of an NDA for SUBA-Itraconazole BCCNS, each \$0.85 increment of each such Advance will be credited and set off against each \$1.00 increment of Royalty owed to the Company, and with respect to each Advance will be credited and set off against each \$1.00 increment of Royalty owed to the Company. In addition, if, prior to June 30, 2021, the Company has not fulfilled the Equity Funding Achievement, Mayne Pharma shall have the right to satisfy all of its remaining Royalty obligations by making a single lump sum payment to the Company in an amount equal to seventy percent (70%) of the fair market value of the remaining royalties payable to the Company as determined by an independent appraisal process. The Third Amended SLA also gives Mayne Pharma the right to convert the Company's rights licensed from Mayne Pharma under the Third Amended SLA to a non-exclusive license if the FDA has not approved an NDA filed by the Company for the Product in part of the Field within eight (8) years from the Effective Date.

#### December 2018 Amended and Restated Sublicense Agreement

The Amended and Restated Sublicense Agreement amends and replaces a similar agreement entered into between the Company and Mayne Pharma International, dated as of May 15, 2015, under which Mayne Pharma International sublicensed to the Company the exclusive U.S. rights to two certain third-party patents relating to the use of itraconazole as a treatment for cancer and age-related macular degeneration (the "Patents"). The Amended and Restated Sublicense Agreement amends the required payments to Mayne Pharma for certain development-related milestone payments related to SUBA-Itraconazole BCCNS and allows for the termination of the Amended and Restated Sublicense Agreement if the Third Amended SLA expires or is terminated. On August 21, 2019, the Company received written notice of termination of the Amended and Restated Sublicense Agreement. Thereafter, on August 27, 2019, the Company and Mayne Pharma International entered into a new Sublicense Agreement, effective August 20, 2019 (the "New Sublicense Agreement"), under which the Company received from Mayne Pharma International a sublicense to the Patents on nearly identical terms as the Amended and Restated Sublicense Agreement (including with respect to licensed field, the licensed indications and the license fees, milestone payments and minimum annual and running royalties that may be owed by the Company to Mayne Pharma International was able to enter into the New Sublicense Agreement because, subsequent to the termination of the Amended and Restated Sublicense Agreement, as well as the terms related to patent prosecution and infringement, reporting and indemnification). Mayne Pharma International was able to enter into the New Sublicense Agreement because, subsequent to the termination of the Amended and Restated Sublicense Agreement, Mayne Pharma International entered into a direct license agreement that the transitional entered into a direct license agreement into the New Sublesense Agreement because, subsequent to the termination of the Amended and Restated S

The New Sublicense Agreement has a term commencing on August 20, 2019 and continuing until the earlier of: (a) the date of expiration of the last to expire Patent; or (b) notice by Mayne Pharma International with immediate effect promptly after termination or expiry of its rights to license the Patents. Mayne Pharma International and the Company have the right to terminate the New Sublicense Agreement upon the occurrence of certain events, including the bankruptcy of a party or breach of a party's obligations under the New Sublicense Agreement (subject to a notice and cure period). Mayne Pharma International may also terminate the New Sublicense Agreement upon the expiration of that certain Third Amended SLA.

#### 2. Liquidity and management's plans:

The Company had cash and cash equivalents of approximately \$1.4 million as of September 30, 2019. Based on the Company's current operational plan and budget, the Company expects that it has sufficient cash to manage its business into the third quarter of 2020, although this estimation assumes the Company does not begin any clinical trials, acquire options or rights to additional drug development opportunities or otherwise face unexpected events, costs or contingencies, any of which could affect the Company's cash requirements. Available resources may be consumed more rapidly than anticipated, potentially resulting in the need for additional funding. Although named as only a nominal defendant in the civil action discussed in Note 5, the Company will have a role due to its technical connection with the matter in dispute. Extended legal proceedings could drain valuable time and resources away from the Company's clinical and pre-clinical programs and may also impede any future efforts to raise additional capital.

The Company intends to finance additional research and development, commercialization and distribution efforts and its working capital needs primarily through:

- proceeds from public and private financings (including, most recently, financing from our majority shareholder, Mayne Pharma) and, potentially, from other strategic transactions;
- royalty revenue from Mayne Pharma from sales in the U.S. (if any) of SUBA-Itraconazole BCCNS upon and assuming approval by FDA (after earned royalties have been applied to any advances due under Third Amended SLA);
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including, potentially, warrants held by our majority shareholder, Mayne Pharma);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would
  receive funding based on out-licensing our product; and
- government or private foundation grants or loans which would be awarded to us to further develop our current and future anti-cancer therapies.

However, there is a risk that none of these plans will be implemented in a manner necessary to sustain the Company for an extended period of time and that the Company will be unable to obtain additional financing when needed on commercially reasonable terms, if at all. If adequate funds are not available when needed, the Company may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require the Company to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on the Company, its viability, its financial condition and its results of operations beyond the third quarter of 2020. In addition, a lack of adequate funds may force the Company to cease operations.

As a result of the foregoing circumstances, there is substantial doubt about our ability to continue as a going concern. The consolidated financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

#### 3. Summary of Significant Accounting Policies:

#### Estimates

The preparation of condensed financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates.

#### 3. Summary of Significant Accounting Policies (continued):

#### Revenue Recognition

The Company currently has no ongoing source of revenues. Miscellaneous income, including interest, is recognized when earned by the Company. Deferred revenue represents cash received for royalties in advance of being earned. Such payments are reflected as deferred revenue until recognized under the Company's revenue recognition policy. Deferred revenue would be classified as current if management believes the Company will be able to recognize the deferred amount as revenue within twelve months of the balance sheet date. Deferred revenue will be recognized when the product is sold and the related royalty is earned. Currently, all deferred revenue is related to the SUBA-Itraconazole BCCNS product, which is yet to be approved by FDA. As such, the Company has determined that 100% of the advances of the royalty received by Mayne Pharma should be classified as a non-current liability. At September 30, 2019, deferred revenue consisted of \$3.0 million of royalties advanced by Mayne Pharma under the Third Amended SLA. There was \$0.5 million in deferred revenue at December 31, 2018.

#### Cash and Cash Equivalents

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. At times, the Company may maintain cash balances in excess of Federal Deposit Insurance Corporation insured amounts which is \$250,000 for substantially all depository accounts. As of September 30, 2019, the Company had approximately \$1.0 million in excess of the amount covered by Federal Deposit Insurance Corporation with one financial institution.

#### Research and Development Expenses

Research and development costs are expensed in the period in which they are incurred and include the expenses paid to third parties who conduct research and development activities on behalf of the Company and purchased in-process research and development.

#### Stock-Based Compensation

The Company accounts for stock-based awards to employees and non-employees using Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718 – Accounting for Share-Based Payments, which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of restricted stock units issued are determined by the Company based predominantly on the trading price of the common stock on the date of grant. Fair value of each common stock option is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of a peer group's common stock and other factors estimated over the expected term of the options. The expected term. The risk-free rate is based on the U.S. Treasury yield.

In applying the Black-Scholes option pricing model for options issued in February 2019 and June 2019 that vest in February 2020, the assumptions were as follows: expected price volatility of 85.4% and 85.33%, respectively; risk-free interest rate of 2.51% and 1.83%, respectively; weighted average expected life in years of 6 and 5 years, respectively; and no dividend yield. The value of these awards is based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award. Forfeitures are recorded as incurred.

#### 3. Summary of Significant Accounting Policies (continued):

#### Income Taxes

Deferred tax assets and liabilities are recognized for future tax consequences attributed to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and are measured using enacted tax rates that are expected to apply to the differences in the periods that they are expected to reverse. These differences occur primarily in share-based compensation.

#### Recent accounting pronouncements:

In February 2016, the FASB issued ASU2016-02, "Leases," which created a new Topic, ASC Topic 842 and established the core principle that a lessee should recognize the assets, representing rights-of-use, and liabilities to make lease payments, that arise from leases. For leases with a term of 12 months or less, a lessee is permitted to make an election under which such assets and liabilities would not be recognized, and lease expense would be recognized generally on a straight-line basis over the lease term. This standard was effective for the Company beginning in 2019 and was adopted by the Company for the year beginning January 1, 2019. The Company has evaluated the impact of this guidance on its financial statements and has determined that it had no material impact, as the Company has no leasing arrangements with terms greater than 12 months.

Management has considered all recent accounting pronouncements issued, but not effective, and does not believe that they will have a significant impact on the Company's financial statements.

#### 4. Stockholders' Equity:

#### Employee Stock Plans

On February 3, 2019, Board members were awarded approximately 3.0 million stock options pursuant to the EIP with an exercise price of \$0.076 and grant date fair value of \$0.054 that vest on the first anniversary of the grant date. The grant date fair value of common stock options was determined using the Black-Scholes model on the date of issuance and the number of shares expected to vest. The total grant date fair value of the February 3, 2019 stock option grants was approximately \$0.2 million. On June 3, 2019, the Company issued 25,000 stock options to its newly appointed Chairman of the Board pursuant to the EIP with an exercise price of \$0.076 and grant date fair value of \$0.05 that vest on February 3, 2020. The grant date fair value of common stock options was determined using the Black-Scholes model on the date of shares expected to vest. The total grant date fair value of the June 3, 2019 stock option grants was approximately \$1,250.

Total stock-based compensation for the nine months ended September 30, 2019 was approximately \$0.2 million and is related to common stock options issued pursuant to the EIP in 2018 and 2019. The expense is classified as general and administrative expense in the accompanying condensed statements of operations. As of September 30, 2019, there were 4,792,685 outstanding common stock options under the EIP of which 2,794,000 were vested. There was approximately \$0.04 million in unamortized stock-based compensation at September 30, 2019.

#### 5. Legal Proceedings:

The Company may from time to time become a party to various legal proceedings arising in the ordinary course of business. Except as discussed below, the Company is not the subject of any pending legal proceedings.

On July 9, 2019, Hedgepath, LLC ("HPLLC"), a stockholder of the Company, filed a civil action captioned Hedgepath, LLC v. Magrab, et al, Civil Action Number 2019-0529-JTL, in the Delaware Court of Chancery (the "Action"). In the complaint in the Action, purportedly brought directly and derivatively on behalf of the Company, HPLLC alleges claims for breach of fiduciary duty, declaratory judgement, and dilution of stockholder equity, against the Company's directors and President and Chief Executive Officer, a former director of the Company, (collectively the "Individual Defendants") and Mayne Pharma in connection with (i) the issuance of certain Company equity securities to Mayne Pharma on or about January 8, 2018, (ii) Mayne Pharma's alleged influence over the timing and conduct of the Company's clinical trials of SUBA-Itraconazole for the treatment of BCCNS, and (iii) previously announced amendments to the Supply and License Agreement, as amended (presently memorialized at the Third Amended SLA), between the Company and Mayne Pharma and certain transactions contemplated thereby. The complaint also alleges claims for breach of fiduciary duty and fraudulent misrepresentation in connection with allegedly false and misleading statements included in Company press releases and filings with the SEC. The complaint seeks unspecified damages, equitable and other relief from the defendants. The Company's director and officer insurance has reimbursed all of the Company's legal costs to date from HPLLC's initial inquiry related to this matter. Legal costs associated directly with the Company as a nominal defendant will be payable by the Company until certain retention amounts are reached. Such costs have been immaterial through September 30, 2019 and are included in general and administrative expenses for the current period. The Company believes the Action is legally and factually baseless, and the named director and officer defendants intend to defend themselves vigorously. On September 27, 2019, the Individual Defendants and Mayne Pharma each filed a Motion to Dismiss the Action, and such motion is pending as of the date of this filing.

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

The following discussion and analysis should be read in conjunction with the Condensed Financial Statements and Notes thereto included elsewhere in this Quarterly Report. This discussion contains certain forward-looking statements that involve risks and uncertainties. The Company's actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Quarterly Report and in the Company's other filings with the SEC. See "Cautionary Note Regarding Forward Looking Statements" below.

As used in this Management's Discussion and Analysis of Financial Condition and Results of Operations, unless otherwise indicated, the terms "the Company", "we", "us", "our" and similar terminology refer to Inhibitor Therapeutics, Inc.

#### **Critical Accounting Policies**

See Note 3 of the Notes to Condensed Financial Statements included in Item 1 of this Quarterly Report for a summary of significant accounting policies and information on recently issued accounting pronouncements.

#### **Results of Operations**

#### For the three months ended September 30, 2019 compared to the three months ended September 30, 2018

Research and Development Expenses. We recognized approximately \$0.4 million in research and development expenses during the three months ended September 30, 2019 compared to approximately \$0.8 million for the three months ended September 30, 2018. Research and development expenses for the three months ended September 30, 2019 primarily included salary expenses and expenses related to preparation for the filing of an Investigational New Drug application for use of SUBA-Itraconazole for prostate cancer. The expenses for the three months ended September 30, 2018 primarily included salary expenses, stock-based compensation, and expenses related to our clinical trial for BCCNS which concluded in 2018. Other expenses in both periods included legal expenses relating to patents and clinical trial insurance. The decrease of \$0.4 million is due primarily to a reduction in clinical trial related expenses as a result of Mayne Pharma assuming control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS in December 2018 and immediately assuming responsibility for all expenses related to exploiting the SUBA-Itraconazole BCCNS product in the BCCNS field in exchange for a 9% quarterly cash royalty and other considerations as discussed in Note 1.

*General and Administrative Expenses.* We recognized approximately \$0.3 million in general and administrative expenses during the three months ended September 30, 2019 compared to \$0.4 million for the three months ended September 30, 2018. General and administrative expenses consisted primarily of compensation and related costs for corporate administrative staff and Board members, facility expenditures, professional fees, consulting and taxes. The decrease is due primarily to a decrease in stock compensation expense during the quarter ended September 30, 2019 primarily due to a majority of outstanding stock options vesting prior to the beginning of the current period as well as the expiration of certain unvested stock options upon the 2019 retirement of our former Chairman of the Board.

Interest Income. We recognized interest income of \$4,373 during the three months ended September 30, 2019 compared to \$3,995 for the three months ended September 30, 2018 for interest earned on cash balances in our money market account.

#### For the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018

Research and Development Expenses. We recognized approximately \$0.9 million in research and development expenses during the nine months ended September 30, 2019 compared to approximately \$2.0 million for the nine months ended September 30, 2018. Research and development expenses for the nine months ended September 30, 2019 primarily included salary expenses and expenses related to preparation for the filing of an Investigational New Drug application for use of SUBA-Itraconazole for prostate cancer. The expenses for the nine months ended September 30, 2018 primarily included salary expenses, stock-based compensation, and expenses related to our clinical trial for BCCNS which concluded in 2018. Other expenses in both periods included legal expenses relating to patents and clinical trial insurance. The decrease of \$1.1 million is due primarily to a reduction in clinical trial related expenses as a result of Mayne Pharma assuming control of the regulatory and clinical development program for SUBA-Itraconazole BCCNS in December 2018 and immediately assuming responsibility for all expenses related to exploiting the SUBA-Itraconazole BCCNS field in exchange for a 9% quarterly cash royalty and other considerations as discussed in Note 1.

*General and Administrative Expenses.* We recognized approximately \$1.2 million in general and administrative expenses during the nine months ended September 30, 2019 compared to approximately \$1.3 million for the nine months ended September 30, 2018. General and administrative expenses in both periods consisted primarily of compensation and related costs for corporate administrative staff and Board members, facility expenditures, professional fees, consulting and taxes. The decrease of approximately \$0.1 million was due primarily to a decrease in stock compensation expense primarily due to a majority of outstanding stock options vesting prior to the beginning of the current period as well as the expiration of certain unvested stock options upon the 2019 retirement of our former Chairman of the Board.

Interest Income. We recognized interest income of \$12,494 during the nine months ended September 30, 2019 compared to \$10,707 for the nine months ended September 30, 2018 for interest earned on cash balances in our money market account.

#### Liquidity and Capital Resources

We had cash and cash equivalents of approximately \$1.4 million as of September 30, 2019. Based on our current operational plan and budget, we expect that we will have sufficient cash to manage our business into the third quarter of 2020, although this estimation assumes we do not begin any clinical trials, acquire options or rights to additional drug development opportunities or otherwise face unexpected events, costs or contingencies, any of which could affect the Company's cash requirements. Available resources may be consumed more rapidly than anticipated, potentially resulting in the need for additional funding. Additionally, and although named as only a nominal defendant in the civil action discussed in Note 5 in the accompanying financial statement, the Company will have a role due to its technical connection with the matter in dispute. Extended legal proceedings could drain valuable time and resources away from the Company's operations (including clinical and pre-clinical programs) and may also impede any future efforts to raise additional capital.

We intend to seek additional financing for our research and development, commercialization and distribution efforts and our working capital needs primarily through:

- proceeds from public and private financings (including, most recently, financing from our majority shareholder, Mayne Pharma);
- royalty revenue from Mayne Pharma from sales in the U.S. (if any) of SUBA-Itraconazole BCCNS upon and assuming approval by FDA (after earned royalties have been applied to any royalties advanced under the Third Amended SLA)
- proceeds from the exercise of outstanding warrants previously issued in private financings to investors (including, potentially, warrants held by our majority shareholder, Mayne Pharma);
- potential partnerships with other pharmaceutical companies to assist in the supply, manufacturing and distribution of our products for which we would expect to receive upfront milestone and royalty payments;
- potential licensing and joint venture arrangements with third parties, including other pharmaceutical companies where we would
  receive funding based on out-licensing our product; and
- government or private foundation grants or loans which would be awarded to us to further develop our current and future anti-cancer therapies.

However, there is a risk that none of these plans will be implemented and that we will be unable to obtain additional financing on commercially reasonable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus operations or to obtain funds through arrangements that may require us to relinquish rights to technologies or potential markets, any of which could have a material adverse effect on our company, our viability, our financial condition and our results of operations beyond the third quarter of 2020. In addition, a lack of adequate funds may force us to cease operations.

As a result of the foregoing circumstances, there is substantial doubt about our ability to continue as a going concern beyond the third quarter of 2020. The consolidated financial statements included herein do not include any adjustments relating to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should we be unable to continue as a going concern.

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

Not required for smaller reporting companies.

#### Item 4. Controls and Procedures

#### Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Quarterly Report, the Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer (the "Certifying Officers"), conducted evaluations of our disclosure controls and procedures. As defined under Sections 13a–15(e) and 15d–15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the term "disclosure controls and procedures" means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including the Certifying Officers, to allow timely decisions regarding required disclosures.

Based on this evaluation, the Certifying Officers have concluded that our disclosure controls and procedures were effective.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during our third fiscal quarter of 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Limitations on the Effectiveness of Internal Controls

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our control have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

#### CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

Certain information set forth in this Quarterly Report on Form10-Q, including in Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" (and the "Liquidity and Capital Resources" section thereof) and elsewhere may address or relate to future events and expectations and as such constitutes "forward-looking statements" within the meaning of the Private Securities Litigation Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to our plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects", "may", "could", "would", "should", "believes", "expects", "anticipates", "estimates", "intends", "plans" or similar expressions. These statements are based upon the current beliefs and expectations of our management and are subject to significant risks and uncertainties, including those detailed in our filings with the SEC. Actual results, including, without limitation: (i) our ability to develop and ultimately commercialize therapeutics, (ii) the application and availability of corporate funds and our need for future funds, or (iii) the timing for beginning, completion, and results of, clinical trials and the FDA's review and/or approval and potential commercial launch of our products and product candidates and regulatory filings related to the same, may differ significantly from those set forth in the forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period. Such factors include, among others,

- acceptance of our business model (namely the repurposing of a specialty formulation of the drug itraconazole for the treatment of cancer, and the potential acquisition or license of other pharmaceutical technologies) by investors and potential commercial collaborators;
- · our future capital requirements and our ability to satisfy our capital needs;
- our ability to commence and complete required clinical trials of our product candidate and obtain approval from the FDA or other regulatory agencies in different jurisdictions;
- matters associated with the fact that Mayne Pharma is our majority stockholder, key licensor and commercial partner;
- · our ability to secure and maintain key development and commercialization partners for our product candidate;
- our ability to obtain, maintain or protect the validity of our owned or licensed patents and other intellectual property;
- our ability to internally develop, acquire or license new inventions and intellectual property;
- our ability to retain key executive members;
- · interpretations of current laws and the passages of future laws, rules and regulations applicable to our business; and
- those risk factors listed under Item 1A of our 2018 Annual Report and other factors detailed from time to time in our other filings with the SEC.

Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Report. We undertake no obligation to publically update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

## PART II. OTHER INFORMATION

#### Item 1. Legal Proceedings

On July 9, 2019, Hedgepath, LLC ("HPPLC"), a stockholder of ours, filed a civil action captioned *Hedgepath, LLC v. Magrab, et al*, Civil Action Number 2019-0529-JTL, in the Delaware Court of Chancery (the "Action"). In the complaint in the Action, purportedly brought directly and derivatively on behalf of us, HPLLC alleges claims for breach of fiduciary duty, declaratory judgement, and dilution of stockholder equity, against our directors and President and Chief Executive Officer, a former director of ours, (collectively the "Individual Defendants") and Mayne Pharma in connection with (i) the issuance of certain equity securities to Mayne Pharma on or about January 8, 2018, (ii) Mayne Pharma's alleged influence over the timing and conduct of our clinical trials of SUBA-Itraconazole for the treatment of BCCNS, and (iii) previously announced amendments to the Supply and License Agreement, as a mended, between us and Mayne Pharma and certain transactions contemplated thereby. The complaint also alleges claims for breach of fiduciary duty and fraudulent misrepresentation in connection with allegedly false and misleading statements included in our press releases and filings with the SEC. The complaint seeks unspecified damages, equitable and other relief from the defendants. Our director and officer insurance has reimbursed all of our legal costs to date from HPLLC's initial inquiry related to this matter. Legal costs associated directly with us as a nominal defendant will be payable by us until certain retention amounts are reached. Such costs were immaterial through September 30, 2019 and are included in general and administrative expenses for the current period. We believe the Action is legally and factually baseless, and the named director and officer defendants intend to defend themselves vigorously. On September 27, 2109, the Individual Defendants and Mayne Pharma each filed a Motion to Dismiss the Action, and such motion is pending as of the date of this filing.

#### Item 1A. Risk Factors.

Not required for smaller reporting companies.

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.

Not applicable.

# **Table of Contents**

Item 6.	Exhibits.
Number	Description
10.1	Sublicense Agreement, dated August 27, 2019, by and between Mayne Pharma International Pty Ltd and the Company (Certain information has been redacted in the marked portions of the exhibit).
31.1	Certification of Chief Executive Officer Pursuant To Sarbanes-Oxley Section 302
31.2	Certification of Chief Financial Officer Pursuant To Sarbanes-Oxley Section 302
32.1	Certification Pursuant To 18 U.S.C. Section 1350 (*)
32.2	Certification Pursuant To 18 U.S.C. Section 1350 (*)
101.ins	XBRL Instance Document
101.sch	XBRL Taxonomy Extension Schema Document
101.cal	XBRL Taxonomy Calculation Linkbase Document
101.def	XBRL Taxonomy Definition Linkbase Document
101.lab	XBRL Taxonomy Label Linkbase Document

101.pre XBRL Taxonomy Presentation Linkbase Document

\* A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

#### SIGNATURES

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

Date: November 7, 2019

Date: November 7, 2019

INHIBITOR THERAPEUTICS, INC.

By: <u>/s/ Nicholas J. Virca</u> Nicholas J. Virca President and Chief Executive Officer (Principal Executive Officer)

By: /s/ Garrison J. Hasara Garrison J. Hasara, CPA Chief Financial Officer and Treasurer (Principal Financial Officer)

S-1

# Redactions with respect to certain portions hereof denoted with "\*\*\*"

Execution Date: August 27, 2019 Effective Date: August 20, 2019

# SUBLICENSE AGREEMENT

#### BETWEEN

## MAYNE PHARMA INTERNATIONAL PTY LTD

&

# INHIBITOR THERAPEUTICS, INC.

#### SUBLICENSE AGREEMENT

THIS SUBLICENSE AGREEMENT (this "Agreement") is executed on August 27, 2019 and entered into effective as of August 20, 2019 by and between MAYNE PHARMA INTERNATIONAL PTY LTD, ABN 88 007 870 984, an Australian body corporate having an address at 1538 Main North Road, Salisbury South, SA 5106, Australia ("Mayne Pharma"), and INHIBITOR THERAPEUTICS, INC. (formerly known as HedgePath Pharmaceuticals, Inc.), a company incorporated in Delaware having an address at 4830 W. Kennedy Blvd, Suite 600, Tampa, Florida, 33609, United States ("INTI") with respect to the following:

#### RECITALS

WHEREAS, valuable inventions entitled "New Angiogenesis Inhibitors" (JHU Ref No C04494; hereinafter referred to as the "**ANGIOGENESIS PATENT**"), and "New uses for old drugs: Identification of Hedgehog Pathway Antagonists previously tested in Humans" (JHU Ref No C04820; hereinafter referred to as the "**HEDGEHOG PATENT**") have heretofore been developed during the course of research conducted by Drs Jun Liu, Curtis Chung, David Sullivan, Schrindar Bhat, Jin Xu and Philip Beachy (all hereinafter "**INVENTORS**");

WHEREAS, THE JOHNS HOPKINS UNIVERSITY, a Maryland corporation having an address at 3400 N. Charles Street, Baltimore, Maryland, 21218-2695 ("**JHU**"), has acquired through assignment all rights, title and interest, with the exception of certain retained rights by the Howard Hughes Medical Institute and the United States Government, in said valuable inventions;

WHEREAS, JHU has granted to Mayne Pharma a sublicense effective August 20, 2019 to commercially develop, manufacture, use and distribute products and processes based upon or embodying said valuable inventions (hereinafter referred to as the "HEAD LICENSE");

WHEREAS, INTI and Mayne Pharma Ventures Pty Ltd ACN 168 896 357 ("MPV"), an affiliate of Mayne Pharma, have entered into that certain Third Amended and Restated Supply and License Agreement dated 17 December 2018 under which MPV agrees to supply INTI with SUBA-Itraconazole hard capsules and provide a license to certain intellectual property rights (hereinafter referred to as the "THIRD SLA"); and

WHEREAS, Mayne Pharma desires to grant, and INTI desires to accept, a sub license of the rights granted to Mayne Pharma under the HEAD LICENSE in the LICENSED FIELD and the TERRITORY (both as hereinafter defined), upon the terms and conditions set forth herein.

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

#### ARTICLE 1 DEFINITIONS

All references to particular Exhibits, Articles or Paragraphs shall mean the Exhibits to, and Paragraphs and Articles of, this Agreement, unless otherwise specified. For the purposes of this Agreement and the Exhibits hereto, the following words and phrases shall have the following meanings:

1.1 "AFFILIATED COMPANY" as used herein in either singular or plural shall mean any corporation, company, partnership, joint venture or other entity, which controls, is controlled by or is under common control with INTI. For purposes of this Paragraph 1.1, control shall mean the direct or indirect ownership of at least fifty- percent (50%).

1.1A "BCCNS FIELD" shall mean the treatment of human patients with Basal Cell Carcinoma Nevus (Gorlin) Syndrome via oral administration.

1.2 "EFFECTIVE DATE" of this License Agreement shall mean August 20, 2019, which is the effective date of the HEAD LICENSE.

1.3 "EXCLUSIVE LICENSE" shall mean a grant by Mayne Pharma to INTI of its entire right and interest as a licensee in the PATENT RIGHTS subject to (i) rights retained by the United States Government, if any, in accordance with the Bayh-Dole Act of 1980 (established by P.L. 96-517 and amended by P.L. 98-620, codified at 35 USC § 200 et. seq. and implemented according to 37 CFR Part 401), and (ii) the retained right of JHU to make, have made, provide and use for its and The Johns Hopkins Health Systems' purposes LICENSED PRODUCT(S) and LICENSED SERVICE(S), including the ability to distribute any biological material disclosed and/or claimed in PATENT RIGHTS for nonprofit academic research use to non-commercial entities as is customary in the scientific community and (iii) the HHMI License.

1.3A "FIRST COMMERCIAL SALE" shall mean the first day of the calendar quarter that occurs after the first sale for use or consumption by the general public of a LICENSED PRODUCT in the LICENSED FIELD in the TERRITORY after all required marketing and pricing approvals have been granted by the US Food and Drug Administration ("FDA").

1.4 "LICENSED FIELD" shall mean (i) for the ANGIOGENESIS PATENT: itraconazole racemic mixture, for the treatment of human patients with any of the LICENSED INDICATIONS via oral administration under the PATENT RIGHTS (and specifically excluding TOPICAL USE); and (ii) for the HEDGEHOG PATENT: SYSTEMIC USE and OCULAR USE of the racemic mixture of itraconazole for the treatment of human patients with any of the LICENSED INDICATIONS via oral administration. The LICENSED FIELD excludes the BCCNS FIELD and any fields not expressly listed above. \*\*\*.

1.4A "LICENSED INDICATIONS" shall mean the following to the extent they are oncology and age-related macular degeneration indications (i) any prostate cancer, prostatic intraepithelial neoplasia (IEN) and benign prostatic hyperplasia, (ii) any lung cancer and atypical adenomatous hyperplasia and (iii) familial adenomatous polyposis, colorectal polyps and Barett's esophagus. The LICENSED INDICATIONS exclude the BCCNS FIELD and any indications not expressly listed above.

1.5 "LICENSED PRODUCT(S)" as used herein in either singular or plural shall mean any process or method, material, compositions, drug, or other product, the manufacture, use or sale of which would constitute, but for the license granted to INTI pursuant to this Agreement, an infringement of a claim of PATENT RIGHTS (infringement shall include, but is not limited to, direct, contributory, or inducement to infringe).

1.6 "LICENSED SERVICE(S)" as used herein in either singular or plural shall mean the performance on behalf of a third party of any method or the manufacture of any product or the use of any product or composition which would constitute, but for the license granted to INTI pursuant to this Agreement, an infringement of a claim of the PATENT RIGHTS, (infringement shall include, but not be limited to, direct, contributory or inducement to infringe).

1.7 "NET SALES" shall mean \*\*\*.

1.8 "NET SERVICE REVENUES" shall mean \*\*\*.

1.9 "PATENT RIGHTS" shall mean (i) US Provisional Application No 60/583,076 (JHU Ref No C04494) entitled "New Angiogenesis Inhibitors", subsequently filed as PCT/US05/23015 on June 27, 2005 (hereinafter referred to as "the ANGIOGENESIS PATENT"); and (ii) US patent No 8,653,083 entitled "Hedgehog Pathway Antagonists to Treat Disease", filed on August 22, 2005, and subsequently filed as PCT/US2006/32952 on August 22, 2006 (hereinafter referred to as "the HEDGEHOG PATENT"); and (iii) the inventions disclosed and claimed therein, and all continuations, divisions and reissued based thereof, and any patents issuing, granted or registered therefrom. INTI acknowledges and agrees that PATENT RIGHTS do not include \*\*\*.

**1.10 "SUBLICENSEE"** shall mean any person or entity to which LICENSEE has granted a sublicense with the approval of Mayne Pharma and JHU under Paragraph 2.2 of this Agreement.

1.11 Not used.

1.12 "OCULAR USE" shall mean application to the membranes, cornea or conjunctiva of the eye.

1.13 "SYSTEMIC USE" shall mean internal application throughout the whole body and not confined to a specific localized external area, including ingested or injected formulations of drugs, but excluding intradermal and subcutaneous injected formulations of drugs designed to locally treat external areas of the body and having a predominately local effect.

1.14 "TOPICAL USE" shall mean application to an external area of the body and affecting mostly the area to which it is applied, including intradermal and subcutaneous injection designed to locally treat such external area, including but not limited to the skin, ear and accessible mucous membranes including but not limited to those of the mouth, vagina and anus. TOPICAL USE shall comprise of drug formulations and delivery mechanisms including but not limited to lotions, creams, ointments, gels, powders (talc), patches, nanoparticles, microneedles and solutions (liquids) but shall exclude systemic uses, such as ingested or injected formulations of drugs. For the purpose of this agreement, TOPICAL USE shall specifically exclude OCULAR USE.

1.15 Not used.

1.16 "TERRITORY" shall mean the United States of America, including all commonwealths, territories and possessions thereof.

1.17 "THIRD PARTY" shall mean any entity other than INTI or any SUBLICENSEE.

#### ARTICLE 2 LICENSE GRANT

2.1 Grant. Subject to the terms and conditions of this Agreement, Mayne Pharma hereby grants to INTI an EXCLUSIVE LICENSE to make, have made, use, import, offer for sale and sell the LICENSED PRODUCT(S) and to provide the LICENSED SERVICE(S) in the TERRITORY under the PATENT RIGHTS in the LICENSED FIELD.

**2.2** No right of Sublicense. INTI may not sublicense to others (including any AFFILIATED COMPANY) under this Agreement, except with prior written consent of Mayne Pharma and JHU, which each may withhold or grant subject to conditions, in its discretion.

**2.3 Government Rights.** The United States Government may have acquired a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the inventions described in PATENT RIGHTS throughout the world. The rights granted herein are additionally subject to: (i) the requirement that any LICENSED PRODUCT(S) produced for use or sale within the United States shall be substantially manufactured in the United States (unless a waiver under 35 USC § 204 or equivalent is granted by the appropriate United States government agency), (ii) the right of the United States government to require JHU, or its licensees, including INTI, to grant sublicenses to responsible applicants on reasonable terms when necessary to fulfill health or safety needs, and, (iii) other rights acquired by the United States government under the laws and regulations applicable to the grant/contract award under which the inventions were made. INTI will reimburse to Mayne Pharma all costs and expenses reasonably incurred in connection with an application for a waiver under 35 USC § 204 or equivalent by the appropriate United States government agency to the extent it relates to the LICENSED FIELD, within \*\*\* days of the receipt of an invoice from Mayne Pharma and reasonable evidence of payment.

2.4 Howard Hughes Medical Institute's Retained License.INTI acknowledges that it has been informed that the HEDGEHOG LICENSED RIGHTS were developed, at least in part, by HHMI employees and that HHMI has a paid up, non-exclusive, irrevocable license to practice the HEDGEHOG LICENSED RIGHTS for research purposes, but with no right to assign or sublicense (the "HHMI License"). This License is explicitly made subject to the HHMI License.

#### ARTICLE 3 FEES, ROYALTIES, PAYMENTS

3.1 License Fee. Mayne Pharma acknowledges that INTI paid a license fee to Mayne Pharma for a license to the PATENT RIGHTS under an earlier sublicense agreement between the Parties effective 31 August 2015 which was subsequently terminated, and no additional license fee is payable under this Agreement.

3.2 Minimum Annual Royalties. INTI shall pay to Mayne Pharma minimum annual royalties as set forth in Exhibit A. These minimum annual royalties shall be due within \*\*\* after the FIRST COMMERCIAL SALE of a LICENSED PRODUCT occurs. Running royalties accrued under Paragraph 3.3 and paid to Mayne Pharma during the \*\*\* of the FIRST COMMERCIAL SALE shall be credited against the minimum annual royalties due on that date. Minimum annual royalties cease to be payable on the earlier of (i) the expiry or lapse of all PATENT RIGHTS that have been granted, issued or registered in the TERRITORY; or (ii) there is no longer a marketing authorization in place for sale of a LICENSED PRODUCT in the LICENSED FIELD in the TERRITORY.

**3.3 Running Royalties.** INTI shall pay to Mayne Pharma a running royalty as set forth in <u>Exhibit A</u>, for each LICENSED PRODUCT(S) sold, and for each LICENSED SERVICE(S) provided, by INTI and any SUBLICENSEE(S), based on NET SALES and NET SERVICE REVENUES for the term of this Agreement. Such payments shall be made quarterly from the FIRST COMMERCIAL SALE of a LICENSED PRODUCT occurs.

#### 3.4 Not used.

**3.5 Milestone Payments.** INTI shall pay to Mayne Pharma milestone payments as set forth in <u>Exhibit A</u>, upon the occurrence of the milestone events described therein whether achieved by (a) INTI or any SUBLICENSEE with respect to a LICENSED PRODUCT in the LICENSED FIELD, or (b) Mayne Pharma or any of its sublicensees with respect to a LICENSED PRODUCT in the BCCNS FIELD. INTI shall provide written notice to Mayne Pharma within \*\*\* of achievement of the milestones numbered 1, 2 and 3 in <u>Exhibit A</u> in the LICENSED FIELD. These milestone payments shall be due within \*\*\* following receipt by INTI of an invoice therefor.

**3.6 Patent Reimbursement.** In accordance with Paragraph 4.1 below, INTI will reimburse Mayne Pharma, within \*\*\* of the receipt of an invoice from Mayne Pharma and reasonable evidence of payment, for all costs associated with the preparation, filing, maintenance, and prosecution of the PATENT RIGHTS in the TERRITORY incurred by JHU subsequent to the EFFECTIVE DATE of this Agreement.

**3.7 Payment.** All payments under this Agreement (including payments under this Article 3 and Paragraph 4.1) shall be payable within \*\*\* after INTI receives an invoice or at any time specified for payment in this Agreement, whichever is the later. Amounts are payable in USD, and where necessary, converted at an average daily exchange rate to buy USD for the applicable calendar quarter to which that payment relates, as published in the Wall Street Journal.

**3.8 Payment Information.** All check payments from INTI to Mayne Pharma shall be sent to such address which Mayne Pharma may designate in writing from time to time. Checks are to be made payable to "Mayne Pharma". Wire transfers may be made to the account which Mayne Pharma may designate in writing from time to time. INTI shall be responsible for any and all costs associated with wire transfers.

**3.9 Late Payments.** In the event that any payment due hereunder is not made when due, the payment shall accrue interest beginning on the \*\*\* following the due date thereof, calculated at the annual rate of the sum of (a) \*\*\* plus (b) \*\*\*, provided however, that in no event shall said annual interest rate exceed the maximum legal interest rate for corporations. Each such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of any party to seek any other remedy, legal or equitable, to which it may be entitled because of the delinquency of any payment including, but not limited to termination of this Agreement as set forth in Paragraph 9.2.

#### 3.10 Withholding tax.

(a) If any payment or deliverable under this Agreement is subject to any tax, duties, levies, charges, fees or other imposts of any kind ("**Taxes**") which INTI is required at law to withhold, then INTI will withhold that amount and deduct it from the payments required to be made to Mayne Pharma under this Agreement. INTI will promptly provide to Mayne Pharma certificates or any other form of documentary evidence issued by any authority regarding the payment of any such Taxes. INTI will sign all lawful documents as reasonably requested by Mayne Pharma as is necessary to able Mayne Pharma to take advantage of any applicable legal provision or any double taxation treaties that would result in limiting the amount of any such Taxes.

(b) Where any sum due to be paid to Mayne Pharma hereunder is subject to any withholding or similar tax, INTI shall use its commercially reasonable efforts to do all such acts and things and to sign all such documents as will enable it to take advantage of any applicable double taxation agreement or treaty. In the event there is no applicable double taxation agreement or treaty, or if an applicable double taxation agreement or treaty reduces but does not eliminate such withholding or similar tax, INTI shall pay such withholding or similar tax to the appropriate government authority, deduct the amount paid from the amount paid to Mayne Pharma and secure and send to Mayne Pharma the best available evidence of such payment.

(c) For any period during the term of this Agreement where there is no applicable double taxation agreement or treaty, to the extent that Mayne Pharma, acting reasonably, is not able to obtain the benefit of any amounts withheld or deducted by INTI under this Agreement, then Mayne Pharma shall give notice of this to INTI and INTI must pay Mayne Pharma such additional amounts as necessary to ensure Mayne Pharma receives, when due, a net amount (after deduction or withholding of Taxes in respect of such additional amounts) equal to the full amount which Mayne Pharma would have received if no deduction or withholding had been made.

#### ARTICLE 4 PATENT PROSECUTION, MAINTENANCE, & INFRINGEMENT

#### 4.1 Prosecution & Maintenance.

4.1.1 Title to all PATENT RIGHTS pursuant to this Agreement shall reside in JHU.

4.1.2 The parties acknowledge that, under the Head License, JHU shall take primary responsibility for the prosecution and maintenance of all PATENT RIGHTS in the TERRITORY. JHU shall have primary responsibility for the PATENT RIGHTS prosecuted and maintained in any jurisdiction in the TERRITORY, and at INTI's expense, shall file, prosecute and maintain all such patents and patent applications that, subject to the terms and conditions of this Agreement, INTI has obtained a license hereunder. JHU shall have full and complete control over all patent prosecution matters in connection therewith under the PATENT RIGHTS in the TERRITORY, provided however, that Mayne Pharma shall (a) timely provide to INTI copies of non-confidential official actions and written correspondence with the USPTO regarding the PATENT RIGHTS in the TERRITORY, and (b) consult with INTI and allow INTI an opportunity to comment, which comments Mayne Pharma will consider and as appropriate, pass onto JHU.

4.1.3 INTI shall be responsible for all reasonable out-of-pocket expenses associated with the filing, prosecution and maintenance of the ANGIOGENESIS PATENTS RIGHTS and the HEDGEHOG PATENT(s) in the TERRITORY. Provided Mayne Pharma has provided INTI with at least \*\*\* advance written notice of any filing or response deadline or fee due date, by written notification to Mayne Pharma at least \*\*\* in advance of any filing or response deadline, or fee due date (or where Mayne Pharma has not provided sufficient advance notice, such shorter period such that INTI has at least \*\*\* to consider its election), INTI may elect not to have a patent application filed or not to pay expenses associated with prosecuting or maintaining any patent application or patent comprising the PATENT RIGHTS, provided that INTI pays for all costs incurred up to receipt of such notification. Failure to provide such notification can be considered to be INTI's authorization to proceed at INTI's expense. Upon such notification, on behalf of Mayne Pharma, JHU may file, prosecute, and/or maintain such patent applications or patent at its own expense and for its own benefit and any rights or license granted hereunder held by INTI or any SUBLICENSEE(S) relating to the PATENT RIGHTS which comprise the subject of such patent applications or patent and/or apply to the TERRITORY, shall terminate.

4.2 Notification. Each party will notify the other promptly in writing when any infringement by another is uncovered or suspected.

#### 4.3 Infringement.

(a) Mayne Pharma shall have the first right to enforce any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY. Subject to Paragraph 4.5A, \*\*\* will pay all reasonable costs and expenses (including reasonable attorney fees for litigation and opinion) incurred by \*\*\* in connection with such enforcement (Enforcement Costs). Before Mayne Pharma commences an action with respect to any infringement of such patents, INTI acknowledges and agrees that Mayne Pharma shall give careful consideration to the views of JHU and to potential effects on the public interest in making its decision whether or not to sue. INTI acknowledges and agrees that no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld. This right to sue for infringement shall not be used in an arbitrary or capricious manner. INTI shall reasonably cooperate in any such litigation at \*\*\* expense, including in accordance with Paragraph

4.6. Should INTI seek the first right to enforce any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY, then it shall notify Mayne Pharma who will, if it consents, seek the consent of JHU (which consent INTI acknowledges may be withheld or granted subject to conditions by JHU acting in its discretion).

(b) If INTI elects not to pay Enforcement Costs in respect of a particular infringement in the TERRITORY, then it shall so notify Mayne Pharma in writing within \*\*\* of receiving notice that an infringement exists, and Mayne Pharma may, in its sole judgment and at its own expense, take steps to enforce any patent and control, settle, and defend such suit in a manner consistent with the terms and provisions hereof, and recover, for its own account, any damages, awards or settlements resulting therefrom, or may allow JHU to do so.

4.4 Patent Invalidity Suit. Mayne Pharma shall have the first right to defend any declaratory judgment action or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS where such action or similar proceeding is brought by a party primarily seeking to compete within LICENSED FIELD in the TERRITORY. Subject to Paragraph 4.5A, \*\*\* will pay all reasonable costs and expenses (including reasonable attorney fees for litigation and opinion) incurred by \*\*\* in connection with such defense. INTI acknowledges and agrees that no settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the prior written consent of JHU, which consent shall not be unreasonably withheld. Should INTI seek the first right to defend any declaratory judgment action or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS within LICENSED FIELD in the TERRITORY, then it shall notify Mayne Pharma who, if it consents, will seek the consent of JHU (which consent INTI acknowledges may be withheld or granted subject to conditions by Mayne Pharma or JHU (as applicable) acting in its discretion). If it is not clear whether a party is primarily seeking to compete within LICENSED FIELD or outside the LICENSED FIELD in the TERRITORY, then JHU may elect to take over the sole defense of the action at its own expense. INTI and Mayne Pharma shall cooperate fully with JHU in connection with any such action at JHU's expense.

4.5 Recovery. Any recovery by Mayne Pharma under Paragraph 4.3 shall be paid:

(a) first to \*\*\* to reimburse its Enforcement Costs; and

(b) following \*\*\* recovery of its Enforcement Costs, the Parties shall share equally in the recovery. If the Enforcement Costs exceed the recovery, then \*\*\* shall be credited against royalties payable by INTI to Mayne Pharma hereunder in connection with sales of LICENSED PRODUCT covered in the PATENT RIGHTS which are the subject of the infringement suit in the TERRITORY, provided, however, that any such credit under this Paragraph shall not exceed \*\*\* of the royalties otherwise payable to Mayne Pharma with regard to sales in the TERRITORY in any one calendar year, with any excess credit being carried forward to future calendar years.

**4.5A Joint litigation committee.** Mayne Pharma shall manage the conduct of any enforcement of any patent within PATENT RIGHTS against any infringement or alleged infringement thereof within LICENSED FIELD in the TERRITORY or defense of any declaration judgment or similar proceeding (including post grant review before any patent office or *inter partes* review before the Patent Trial and Appeal Board of the USPTO) alleging invalidity of any of the PATENT RIGHTS within LICENSED FIELD in the TERRITORY at its sole discretion, subject to:

(a) consulting with INTI through a joint litigation committing comprising two appointees of each of Mayne Pharma and INTI, which committee will discuss the management and course of action with respect to such enforcement or defense, including without limitation, the selection of outside counsel, legal strategy, staff, the engagement of any third party consultants, experts or vendors, the advancement of any legal theory or basis for infringement or defense, scope of discovery, deadlines or extensions for discovery, filing of motions, taking of depositions, providing admission or stipulations, schedule for hearings, proceedings before the court, filing of appeals, commencement and conduct of settlement negotiations or any other actions affecting a Party's rights or obligations or entailing the incurring of cost or expense; and

(b) Mayne Pharma obtaining the express consent of INTI prior to selecting counsel, bringing any suit in INTI's name, or entering into any settlement, consent judgment or other voluntary final disposition of the suit, such consent not be unreasonably withheld, except that if JHU consents to INTI enforcing any patent within the PATENT RIGHTS or defending any declaratory judgment action or similar proceeding alleging invalidity of any of the PATENT RIGHTS then INTI shall manage the conduct of any such enforcement or defense but will consult with Mayne Pharma on the same terms as would have applied under Paragraph 4.5A(a) and obtain the prior written consent of Mayne Pharma prior to the events referred to in Paragraph 4.5A(b), such consent not be unreasonably withheld.

**4.6 Conduct of litigation where INTI is a party.** Where it is necessary or desirable for INTI to be named as a party in any litigation referred to in Paragraph 4.3 or 4.4, INTI will do all acts and execute such legal papers as are reasonably requested by Mayne Pharma in connection with such litigation. The counsel selected by Mayne Pharma for the litigation (subject to the express consent of INTI, not to be unreasonably withheld) shall represent both INTI and Mayne Pharma. Notwithstanding the foregoing, if due to legal conflict, the parties cannot be represented by the same counsel, then each of JHU and Mayne Pharma shall have the right to retain its own separate legal counsel, in which case, the fees of such separate legal counsel shall still be paid by INTI.

**4.7 Listing on the FDA Orange Book.** At the applicable time, INTI must use reasonable commercial efforts to list all patents comprised in the PATENT RIGHTS promptly in the FDA Orange Book for the LICENSED PRODUCT in the LICENSED FIELD.

#### ARTICLE 5 OBLIGATIONS OF THE PARTIES

5.1 Reports. INTI shall provide to Mayne Pharma the following written reports according to the following schedules.

(a) INTI shall provide quarterly Royalty Reports, substantially in the format of Exhibit B and due within \*\*\* the FIRST COMMERCIAL SALE occurs. Royalty Reports shall disclose the amount of LICENSED PRODUCT(S) and LICENSED SERVICE(S) sold, the total NET SALES and NET SERVICE REVENUES of such LICENSED PRODUCT(S) and LICENSED SERVICE(S), and the running royalties due to Mayne Pharma as a result of NET SALES and NET SERVICE REVENUES by INTI or any SUBLICENSEE thereof. Payment of any such royalties due shall accompany such Royalty Reports.

(b) Until INTI or any SUBLICENSEE has achieved a first commercial sale of a LICENSED PRODUCT or LICENSED SERVICE in the TERRITORY, or received FDA market approval, INTI shall provide to Mayne Pharma semiannual Diligence Reports, due within \*\*\* following the EFFECTIVE DATE of this Agreement. These Diligence Reports shall describe the technical efforts of INTI or SUBLICENSEE towards meeting its obligations under the terms of this Agreement.

(c) INTI shall provide to Mayne Pharma Annual Reports within \*\*\* following the EFFECTIVE DATE of this Agreement. Annual Reports shall include:

- (i) evidence of insurance as required under Paragraph 10.4, or, a statement of why such insurance is not currently required, and
- (ii) notice of all FDA approvals of any LICENSED PRODUCT(S) or LICENSED SERVICE(S) obtained by INTI or any SUBLICENSEE, the patent(s) or patent application(s) licensed under this Agreement upon which such product or service is based, and the commercial name of such product or service, or, in the alternative, a statement that no FDA approvals have been obtained.

**5.2 Records.** INTI shall make and retain, for a period of \*\*\* following the period of each report required by Paragraph 5.1, true and accurate records, files and books of account containing all the data reasonably required for the full computation and verification of sales and other information required in Paragraph 5.1. Such books and records shall be in accordance with generally accepted accounting principles consistently applied. INTI shall permit the inspection and copying of such records, files and books of account by Mayne Pharma, JHU or their agents during regular business hours upon \*\*\* written notice to INTI. Such inspection shall not be made more than once each calendar year. All costs of such inspection and copying shall be paid by \*\*\*, provided that if any such inspection by Mayne Pharma or JHU shall reveal that an error has been made in the amount equal to \*\*\* or more of such payment, such costs shall be borne by \*\*\*.

**5.3 Best Efforts.** INTI is responsible for the commercialization of the LICENSED PRODUCT(S) and LICENSED SERVICE(S) in the LICENSED FIELD in the TERRITORY, including the conduct of all development programs, the submission and approval of the marketing authorizations, and payment of all associated fees and expenses, provided that JHU and Mayne Pharma must provide any assistance reasonably requested by INTI in seeking marketing authorizations (at INTI's expense). INTI shall exercise best efforts to develop and to introduce the LICENSED PRODUCT(S) in the LICENSED FIELD into the commercial market as soon as practicable, consistent with sound and reasonable business practice and judgement; thereafter, until the expiration or termination of this Agreement, INTI shall endeavor to keep LICENSED PRODUCT(S) in the LICENSED FIELD reasonably available to the public. INTI shall also exercise reasonable efforts to develop LICENSED PRODUCT(S) suitable for different indications within the LICENSED FIELD, so that the PATENT RIGHTS can be commercialized as broadly and as speedily as good scientific and business judgement would deem possible.

**5.4 Patent Acknowledgement.** INTI agrees that all packaging containing individual LICENSED PRODUCT(S)sold by INTI or any SUBLICENSEE will be marked with the number of the applicable patent(s) licensed hereunder in accordance with patent laws in the TERRITORY.

#### ARTICLE 6 REPRESENTATIONS

**6.1 Duties of the Parties.** JHU is not a commercial organization. It is an institute of research and education. Therefore, JHU has no ability to evaluate the commercial potential of any PATENT RIGHTS or LICENSED PRODUCT or other license or rights granted in this Agreement. It is therefore incumbent upon INTI to evaluate the rights and products in question, to examine the materials and information provided by JHU, and to determine for itself the validity of any PATENT RIGHTS, its freedom to operate, and the value of any LICENSED PRODUCTS or SERVICES or other rights granted.

6.2 PATENT RIGHTS PROVIDED "AS IS"; Representations by JHU.JHU has warranted via the Head License that it has good and marketable title to the inventions claimed under PATENT RIGHTS with the exception of certain retained rights of HHMI the United States Government, which may apply if any part of the JHU research was funded in whole or in part by the United States Government. JHU does not warrant the validity of any patents or that practice under such patents shall be free of infringement. EXCEPT AS EXPRESSLY SET FORTH IN THIS PARAGRAPH 6.2, EACH OF INTI AND ANY SUBLICENSEE AGREE THAT THE PATENT RIGHTS ARE PROVIDED "AS IS", AND THAT EACH OF JHU AND MAYNE PHARMA MAKE NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE PERFORMANCE OF LICENSED PRODUCT(S) AND LICENSED SERVICE(S) INCLUDING THEIR SAFETY, EFFECTIVENESS, OR COMMERCIAL VIABILITY. EACH OF JHU AND MAYNE PHARMA DISCLAIM ALL WARRANTIES WITH REGARD TO PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, ALL WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE. NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, JHU ADDITIONALLY DISCLAIMS ALL OBLIGATIONS AND LIABILITIES ON THE PART OF JHU AND INVENTORS, AND

MAYNE PHARMA ADDITIONALLY DISCLAIM ALL OBLIGATIONS AND LIABILTIES ON THE PART OF MAYNE PHARMA FOR DAMAGES, INCLUDING, BUT NOT LIMITED TO, DIRECT, INDIRECT, SPECIAL, AND CONSEQUENTIAL DAMAGES, ATTORNEYS' AND EXPERTS' FEES, AND COURT COSTS (EVEN IF ANY OF JHU OR MAYNE PHARMA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, FEES OR COSTS), ARISING OUT OF OR IN CONNECTION WITH THE MANUFACTURE, USE, OR SALE OF THE PRODUCT(S) AND SERVICE(S) LICENSED UNDER THIS AGREEMENT. INTI AND ANY SUBLICENSEE ASSUME ALL RESPONSIBILITY AND LIABILITY FOR LOSS OR DAMAGE CAUSED BY A PRODUCT AND/OR SERVICE MANUFACTURED, USED, OR SOLD BY INTI OR ANY SUBLICENSEE WHICH IS A LICENSED PRODUCT(S) OR LICENSED SERVICE(S) AS DEFINED IN THIS AGREEMENT.

#### 6.3 Representations and Covenants of Mayne Pharma.

(a) Mayne Pharma warrants to INTI that (i) it is entitled to grant INTI the sublicence of the PATENT RIGHTS on the terms and conditions set out in this Agreement; and (ii) <u>Exhibit C</u> (with commercial in confidence information redacted) is a true and complete copy of the Head License; and (iii) it has not, and will not during the term of this Agreement, impose in favor of any third party any mortgage, pledge, lien, encumbrance, charge or other security interest over the Sublicense or any PATENT RIGHTS, whether that mortgage, pledge, lien, encumbrance, charge or other security interest has a material, adverse impact on INTI's rights under this Agreement.

(b) Mayne Pharma covenants to INTI that it will use reasonable commercial efforts to comply with its obligations under the Head License and will not terminate the Head License without cause except with the prior written consent of INTI, such consent not to be unreasonably withheld or delayed.

#### ARTICLE 7 INDEMNIFICATION

7.1 Indemnification. INTI shall be responsible for injuries or losses to third parties arising from or related to INTI's own acts or omissions, or caused by arising from INTI's use or third party use of LICENSED PRODUCT(S) sold by INTI or any SUBLICENSEE and LICENSED SERVICE(S) performed by INTI or any SUBLICENSEE, or arising as a consequence of the exercise by INTI or any SUBLICENSEE(S) of any rights granted in this Agreement. JHU and the Inventors will have no legal liability exposure to third parties if JHU does not license the LICENSED PRODUCT(S) and LICENSED SERVICE(S), and any royalties JHU and the Inventors may receive under the Head License is not adequate compensation for such legal liability exposure. Therefore, JHU requires INTI to protect JHU and Inventors from such exposure to the same manner and extent to which insurance, if available, would protect JHU and Inventors. Furthermore, JHU and the Inventors will not, under the provisions of the Head License, this Agreement or otherwise, have control over the manner in which INTI or any SUBLICENSEE(S) or those operating for its account or third parties who purchase LICENSED PRODUCT(S) or LICENSED SERVICE(S) from any of the foregoing entities, develop, manufacture, market or practice the inventions of LICENSED PRODUCT(S) and LICENSED SERVICE(S). Therefore,

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Page 12
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INTI and any SUBLICENSEE shall indemnify, defend with counsel reasonably acceptable to JHU, and hold JHU, The Johns Hopkins Health Systems, their present and former trustees, officers, Inventors of PATENT RIGHTS (other than HHMI employees), agents, faculty, employees and students harmless as against any judgments, fees, expenses, or other costs arising from or incidental to any product liability or other lawsuit, claim, demand or other action brought as a consequence of the practice of said inventions by any of the foregoing entities, whether or not JHU or said Inventors, either jointly or severally, is named as a party defendant in any such lawsuit and whether or not JHU or the Inventors are alleged to be negligent or otherwise responsible for any injuries to persons or property. Practice of the inventions covered by LICENSED PRODUCT(S) and LICENSED SERVICE(S), by an agent or any SUBLICENSEE(S) or a third party on behalf of or for the account of INTI or by a third party who purchases LICENSED PRODUCT(S) and LICENSED SERVICE(S) from INTI, shall be considered INTI's practice of said inventions for purposes of this Paragraph. The obligation of INTI to defend and indemnify as set out in this Paragraph shall survive the termination of this Agreement, shall continue even after assignment of rights and responsibilities to an AFFILIATED COMPANY (but not any other assignment by INTI in accordance with Paragraph 10.8), and shall not be limited by any other limitation of liability elsewhere in this Agreement.

7.2 HHMI Indemnification. The Howard Hughes Medical Institute ("HHMI"), and its trustees, officers, employees, and agents (collectively, "HHMI INDEMNITEES"), will be indemnified, defended by counsel reasonably acceptable to HHMI, and held harmless by INTI from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "Claims"), based upon, arising out of, or otherwise relating to this Agreement, including without limitation any cause of action relating to product liability. The previous sentence will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI INDEMNITEE. Notwithstanding any other provision of this Agreement, INTI's obligation to defend, indemnify and hold harmless the HHMI INDEMNITEES under this paragraph will not be subject to any limitation or exclusion of liability or damages or otherwise limited in any way. This provision shall survive the expiration or termination of this Agreement.

7.2 Indemnification Procedure. A party intending to claim indemnification under this Agreement ('Indemnitee'') shall promptly notify the indemnifying party ("Indemnitor") in writing of any lawsuit, claim, demand or other action, or any judgments, fees, expenses or other costs in respect of which the Indemnitee intends to claim such indemnification. In the case of any HHMI INDEMNITEE, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of any HHMI INDEMNITEE to give reasonably prompt notice to an Indemnitor of any such claim shall not affect the rights of such HHMI INDEMNITEE unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects the Indemnitor. The Indemnitee reasonably shall cooperate with the Indemnitor in the defense of the lawsuit, claim, demand or other action, and the Indemnitor shall have the right to control the defense and/or settlement of the lawsuit, claim, demand or other action, provided, however, that any such settlement shall not require the Indemnitee (a) to admit any liability; (b) to pay any amounts; (c) impose any restriction on any HHMI INDEMNITEE's conduct of any of its activities; or (d) not include an unconditional release of all HHMI INDEMNITEEs from all liability for claims that are the subject matter of the settled Claim, without the prior written consent of such Indemnitee. The Indemnitee shall use reasonable efforts to mitigate any fees, expenses or other costs.

#### ARTICLE 8 CONFIDENTIALITY

**8.1 Confidentiality.** If necessary, the parties will exchange information in respect of the subject matter of this Agreement, which they consider to be confidential. The recipient of such information agrees to keep it confidential provided such information is marked as confidential at the time it is sent to the recipient, or if it is disclosed orally, summarised in writing and identified as 'confidential' within \*\*\* after its presentation (provided that a failure to do so shall not detract from the obligations in this Paragraph where it was reasonably apparent that such information was confidential in nature). Without limitation, the recipient agrees to employ all reasonable efforts to maintain the information secret and confidential, such efforts to be no less than the degree of care employeed by the recipient to preserve and safeguard its own confidential information. The information shall not be disclosed or revealed to anyone except employees of the recipient who have a need to know the information and who have entered into a secrecy agreement with the recipient under which such employees are required to maintain confidential the proprietary information of the recipient and such employees shall be advised by the recipient of the confidential nature of the information and that the information shall be treated accordingly.

The obligations of this Paragraph 8.1 shall also apply to any SUBLICENSEE(S) provided such information by INTI. Mayne Pharma's, INTI's, and SUBLICENSEES' obligations under this Paragraph 8.1 shall extend until \*\*\* after the termination of this Agreement.

The obligations of this Paragraph 8.1 shall apply to confidential information exchanged prior to, on or after the EFFECTIVE DATE in connection with this Agreement or the transactions contemplated under it. To avoid doubt, the parties agree that nothing in this Agreement detracts from the restrictions on use and disclosure of confidential information under the Second Amended and Restated Supply and License Agreement, dated May 15, 2015, by and between Mayne Pharma Ventures Pty Ltd., an Affiliated Company of Mayne Pharma, and INTI.

8.2 Exceptions. The recipient's obligations under Paragraph 8.1 shall not extend to any part of the information:

(a) that can be demonstrated to have been in the public domain or publicly known and readily available to the trade or the public prior to the date of the disclosure; or

(b) that can be demonstrated, from written records to have been in the recipient's possession or readily available to the recipient from another source not under obligation of secrecy to the disclosing party prior to the disclosure; or

(c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by the recipient;

(d) that is demonstrated from written records to have been developed by or for the receiving party without reference to confidential information disclosed by the disclosing party.

(e) that is required to be disclosed by law, government regulation or court order, or any applicable stock exchange.

**8.3 Right to Publish.** JHU may publish manuscripts, abstracts or the like describing the PATENT RIGHTS and inventions contained therein provided confidential information of INTI as contemplated in Paragraph 8.1, is not included or without first obtaining approval from INTI to include such confidential information. Otherwise, JHU and the Inventors shall be free to publish manuscripts and abstracts or the like directed to the work done at JHU related to the licensed technology without prior approval.

#### ARTICLE 9 TERM & TERMINATION

9.1 Term. The term of this Agreement shall commence on the EFFECTIVE DATE and shall continue until the earlier of: (a) the date of expiration of the last to expire patent included within PATENT RIGHTS in the TERRITORY; or (b) notice by Mayne Pharma with immediate effect promptly after termination or expiry of the Head License in circumstances where Mayne Pharma no longer has the right to obtain an EXCLUSIVE LICENSE to make, have made, use, import, offer for sale and sell the LICENSED PRODUCT(S) and to provide the LICENSED SERVICE(S) in the TERRITORY under the PATENT RIGHTS in the LICENSED FIELD.

**9.2 Termination By Either Party.** This Agreement may be terminated by either party giving written notice to the other party, with effect immediately (or any later date specified in the notice), in the event that the other party (a) files or has filed against it a petition under the Bankruptcy Act, makes an assignment for the benefit of creditors, has a receiver appointed for it or a substantial part of its assets, otherwise takes advantage of or has any action taken in respect of it under any statute or law designed for relief of debtors, or (having regard to its legal structure and the jurisdiction in which it is incorporated or operates) any event analogous to one of the foregoing events happens to it or (b) fails to perform or otherwise breaches any of its obligations hereunder, if either (i) following the giving of notice by the terminating party of its intent to terminate and stating the grounds therefor, the party receiving such notice shall not have cured the failure or breach within **\*\*\*** or (ii) that failure to perform or breach is not capable of being cured. In no event, however, shall such notice or intention to terminate be deemed to waive any rights to damages or any other remedy which the party giving notice of breach.

9.3 Termination by Mayne Pharma. Mayne Pharma may terminate this Agreement with immediate effect by notice to INTI if the THIRD SLA expires or is terminated.

**9.4 Obligations and Duties upon Termination.** If this Agreement is terminated, both parties shall be released from all obligations and duties imposed or assumed hereunder to the extent so terminated, except as expressly provided to the contrary in this Agreement. Upon termination, both parties shall cease any further use of the confidential information disclosed to the receiving

party by the other party. Termination of this Agreement, for whatever reason, shall not affect the obligation of either party to make any payments for which it is liable prior to or upon such termination. Termination shall not affect Mayne Pharma's right to recover unpaid royalties, fees, reimbursement for patent expenses, or other forms of financial compensation incurred prior to termination. Upon termination INTI shall submit a final royalty report to Mayne Pharma and any royalty payments, fees, unreimbursed patent expenses and other financial compensation due Mayne Pharma shall become immediately payable. Furthermore, upon termination of this Agreement, as between Mayne Pharma and INTI, all rights in and to the licensed technology shall revert immediately to Mayne Pharma at no cost to Mayne Pharma.

#### ARTICLE 10 MISCELLANEOUS

#### 10.1 Use of Name.

10.1.1 INTI and any SUBLICENSEE shall not use the name of The Johns Hopkins University or The Johns Hopkins Health System or any of its constituent parts, such as the Johns Hopkins Hospital or any contraction thereof or the name of Inventors in any advertising, promotional, sales literature or fundraising documents without prior written consent from an authorized representative of JHU. INTI and any SUBLICENSEE(S) shall allow at least fourteen \*\*\* notice of any proposed public disclosure for JHU's review and comment or to provide written consent.

**10.1.2** Mayne Pharma acknowledges that under HHMI policy, Mayne Pharma, AFFILIATED COMPANIES and SUBLICENSEE(S) may not use the name of HHMI or of any HHMI employee (including Dr. Beachy) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference to the name of HHMI or any HHMI employees, including Dr. Beachy, in press releases or similar materials intended for public release is approved by HHMI in advance.

**10.2 No Partnership.** Nothing in this Agreement shall be construed to create any agency, employment, partnership, joint venture or similar relationship between the parties other than that of a licensor/licensee. Neither party shall have any right or authority whatsoever to incur any liability or obligation (express or implied) or otherwise act in any manner in the name or on the behalf of the other, or to make any promise, warranty or representation binding on the other.

**10.3 Notice of Claim.** Each party shall give the other or its representative immediate notice of any suit or action filed, or prompt notice of any claim made, against them arising out of the performance of this Agreement or arising out of the practice of the inventions licensed hereunder.
10.4 Product Liability. Prior to initial human testing or first commercial sale of any LICENSED PRODUCT(S) or LICENSED SERVICE(S) in the LICENSED FIELD in the TERRITORY, INTI shall establish and maintain product liability or other appropriate insurance coverage in the minimum amount of \*\*\* per claim and will annually present evidence to JHU or Mayne Pharma that such coverage is being maintained. Upon JHU's or Mayne Pharma's request, INTI will furnish it with a Certificate of Insurance of each product liability insurance policy obtained. Each of JHU, HHMI and Mayne Pharma shall be listed as an additional insured in INTI's said insurance policies. If such Product Liability insurance is underwritten on a 'claims made' basis, INTI agrees that any change in underwriters during the term of this Agreement will require the purchase of 'prior acts' coverage to ensure that coverage will be continuous throughout the term of this Agreement.

**10.5 Governing Law.** For consistency with the Head License which is with JHU (a Maryland corporation) and are governed by the laws of the State of Maryland, this Agreement shall be construed, and legal relations between the parties hereto shall be determined, in accordance with the laws of the State of Maryland applicable to contracts solely executed and wholly to be performed within the State of Maryland without giving effect to the principles of conflicts of laws. Subject to Paragraph 10.5A, any disputes between the parties to the Agreement shall be brought in the state or federal courts of Maryland. EACH PARTY WAIVES ALL RIGHTS TO ANY TRIAL BY JURY IN ALL LITIGATION RELATING TO OR ARISING OUT OF THIS AGREEMENT.

**10.5A Resolution of Disputes.** A party must not start court proceedings (except proceedings seeking interlocutory relief for the protection of intellectual property or confidential information, or proceedings in relation to debt recovery) for a dispute arising out of this Agreement, including the breach, termination or invalidity of this Agreement, (**\*Dispute**") unless it has complied with this Paragraph 10.5A. A party claiming that a Dispute has arisen must notify the other party giving details of the Dispute. When such a notice is given, each party's respective representatives must first attempt to resolve the Dispute and, if they cannot resolve the Dispute within **\*\*\*** after the notice is given, they must refer the Dispute to each party's chief executive officer who must then attempt to resolve it. If the parties cannot resolve the Dispute to arbitration. If either party exercises that right, the Dispute must be settled by arbitration in accordance with the expedited procedure set out in the Singapore Internation will be Singapore. There will only be one arbitrator. The arbitration must be conducted in English. The decision of the arbitrator shall be final and binding and any award rendered thereon may be entered in any court having jurisdiction. The parties hereby waive any and all objections and defenses to such jurisdiction regardless of the nature of such objection or defense. No dispute affecting the rights or property of HHMI shall be subject to mediation, arbitration or structured negotiations as provided herein.

**10.6 Notice.** All notices or communication required or permitted to be given by either party hereunder shall be deemed sufficiently given if mailed by registered mail or certified mail, return receipt requested, to the other party at its respective address set forth below or to such other address as one party shall give notice of to the other from time to time hereunder.

If to Mayne Pharma:	General Counsel Mayne Pharma International Pty Ltd 1538 Main North Road, Salisbury South, SA 5106 Melbourne Vic 3000 Australia Facsimile: +61 3 9614 7022
If to INTI:	President and CEO INHIBITOR Therapeutics, Inc. 4830 W. Kennedy Blvd., Ste 600 Tampa, Florida 33609, United States Facsimile: +1 813-830-7489

A notice given in accordance with Paragraph 10.6 takes effect when taken to be received (or at a later time specified in it), and is taken to be received: (i) if hand delivered or sent by reputable international courier, on delivery; (ii) if sent by prepaid post, on the third business day after the date of posting (or on the seventh business day after the date of posting if posted to or from a place outside Australia); or (iii) if sent by facsimile, when the sender's facsimile system generates a message confirming successful transmission of the entire notice unless, within 8 business hours after the transmission, the receipient informs the sender that it has not received the entire notice, but if the delivery, receipt or transmission is not on a business day or is after 5.00pm on a business day, the notice is taken to be received at 9.00am on the next business day.

10.7 Compliance with All Laws. In all activities undertaken pursuant to this Agreement, both Mayne Pharma and INTI covenant and agree that each will in all material respects comply with such Federal, state and local laws and statutes, as may be in effect at the time of performance and all valid rules, regulations and orders thereof regulating such activities.

**10.8 Successors and Assigns.** Neither this Agreement nor any of the rights or obligations created herein, except for the right to receive any remuneration hereunder, may be assigned or novated by either party, in whole or in part, without the prior written consent of the other party (which consent must not be unreasonably withheld or delayed), except that either party shall be free to assign or novate this Agreement in connection with any sale of substantially all of its assets without the consent of the other and Mayne Pharma shall be free to assign or novate this Agreement to an AFFILIATED COMPANY who is an assignee of Mayne Pharma's rights and obligations under the Head License. This Agreement shall bind and inure to the benefit of the successors and permitted assigns of the parties hereto.

**10.9 No Waivers; Severability.** No waiver of any breach of this Agreement shall constitute a waiver of any other breach of the same or other provision of this Agreement, and no waiver shall be effective unless made in writing. Any provision hereof prohibited by or unenforceable under any applicable law of any jurisdiction shall as to such jurisdiction be deemed ineffective and deleted herefrom without affecting any other provision of this Agreement. It is the desire of the parties hereto that this Agreement be enforced to the maximum extent permitted by law, and should any provision contained herein be held by any governmental agency or court of competent jurisdiction to be void, illegal and unenforceable, the parties shall negotiate in good faith for a substitute term or provision which carries out the original intent of the parties.

**10.10 Entire Agreement; Amendment.** INTI and Mayne Pharma acknowledge that they have read this entire Agreement and that this Agreement, including the attached Exhibits constitutes the entire understanding and contract between the parties hereto and supersedes any and all prior or contemporaneous oral or written agreements or communications with respect to the subject matter hereof, all of which agreements and communications are merged herein. It is expressly understood and agreed that (i) there being no expectations to the contrary between the parties hereto, no usage of trade, verbal agreement or another regular practice or method dealing within any industry or between the parties hereto shall be used to modify, interpret, supplement or alter in any manner the express terms of this Agreement; and (ii) this Agreement shall not be modified, amended or in any way altered except by an instrument in writing signed by both of the parties hereto.

**10.11 Delays or Omissions.** Except as expressly provided herein, no delay or omission to exercise any right, power or remedy accruing to any party hereto, shall impair any such right, power or remedy to such party nor shall it be construed to be a waiver of any such breach or default, or an acquiescence therein, or in any similar breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character on the part of any party of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in writing and shall be effective only to the extent specifically set forth in such writing. All remedies either under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

**10.12 Force Majeure.** If either party fails to fulfill its obligations hereunder (other than an obligation for the payment of money), when such failure is due to an act of God, or other circumstances beyond its reasonable control, including but not limited to fire, flood, civil commotion, riot, war (declared and undeclared), revolution, or embargoes, then said failure shall be excused for the duration of such event and for such a time thereafter as is reasonable to enable the parties to resume performance under this Agreement, provided however, that in no event shall such time extend for a period of more than \*\*\*. If a failure to perform continues for more than \*\*\*, the other party may terminate this Agreement immediately by giving notice to the affected party.

**10.13 Further Assurances.** Each party shall, at any time, and from time to time, prior to or after the EFFECTIVE DATE of this Agreement, at reasonable request of the other party, execute and deliver to the other such instruments and documents and shall take such actions as may be required to more effectively carry out the terms of this Agreement.

**10.14 Survival.** All representations, warranties, covenants and agreements made herein and which by their express terms or by implication are to be performed after the execution and/or termination hereof, or are prospective in nature, shall survive such execution and/or termination, as the case may be. This shall include Paragraph 3.7 (Payment), 3.10 (Withholding tax) 5.2 (Records), 10.5.1 (Third Party Beneficiaries) and Articles 6, 7, 8, 9 and 10, and Paragraphs 4.3 to 4.6 where Mayne Pharma elects to continue with such litigation after execution and/or termination.

### 10.15 No Third Party Beneficiaries.

10.15.1 HHMI is not a party to this Agreement and has no liability to Mayne Pharma, any of its AFFILIATED COMPANIES or SUBLICENSEEs, or any user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

10.15.2 Nothing in this Agreement shall otherwise be construed as giving any other person, firm, corporation or other entity, other than the parties hereto and their successors and permitted assigns, any right, remedy or claim under or in respect of this Agreement or any provision hereof.

10.16 Headings. Article headings are for convenient reference and not a part of this Agreement. All Exhibits are incorporated herein by this reference.

**10.17 Counterparts.** This Agreement may be executed in counterparts (including electronic counterparts), each of which shall be deemed an original and all of which when taken together shall be deemed but one instrument. Any signature, including any electronic symbol or process affirmatively attached to or associated with this AGREEMENT and adopted by JHU or LICENSEE to sign, authenticate, or accept such contract or record acceptance of the AGREEMENT, hereto shall have the same legal validity and enforceability as a manually executed signature or use of a paper-based recordkeeping system to the fullest extent permitted by applicable law, including the Federal Electronic Signatures in Global and National Commerce Act or any state law based on the Uniform Electronic Transactions Act, and the parties hereby waive any objection to the contrary.

10.18 Costs. Each party must bear its own costs of preparing and executing this Agreement.

#### [Signature page follows]

IN WITNESS WHEREOF, Mayne Pharma and INTI have duly executed this Amended and Restated Sublicense Agreement as of the date first written above.

## MAYNE PHARMA INTERNATIONAL PTY LTD

/s/ Scott Richards Scott Richards CEO

August 26, 2019 (Date)

## INHIBITOR THERAPEUTICS, INC.

/s/ Nicholas J. Virca Nicholas J. Virca President and CEO

August 26, 2019 (Date)

## EXHIBIT A

Minimum annual royalty: \*\*\* per year, commencing in accordance with Paragraph 3.2.

**Royalty:** \*\*\* of NET SALES of an itraconazole LICENSED PRODUCT in the LICENSED FIELD and NET SERVICE REVENUES in the LICENSED FIELD in the TERRITORY where a patent comprised in the PATENT RIGHTS is and remains registered at the time the relevant sales revenues and fees are billed.

Where an itraconazole LICENSED PRODUCT has exclusivity in the LICENSED FIELD in the TERRITORY due solely to the PATENT RIGHTS, a further royalty supplement of \*\*\* of NET SALES and NET SERVICE REVENUES in the TERRITORY.

**Milestone Payments:** INTI shall pay to Mayne Pharma the milestone payments set forth below, **in each case payable only** provided that any claim in the HEDGEHOG PATENT in the TERRITORY directed to administering orally itraconazole remains valid at the time payment falls due:

\*\*\*

# EXHIBIT B

## **Royalty Report**

\*\*\*

# EXHIBIT C

## Head License

### Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)

I, Nicholas J. Virca, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inhibitor Therapeutics, 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 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 as applicable, 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 7, 2019

/s/ Nicholas J. Virca Nicholas J. Virca President and Chief Executive Officer I, Garrison J. Hasara, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inhibitor Therapeutics, 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 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 as applicable, 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 7, 2019

/s/ Garrison J. Hasara Garrison J. Hasara Chief Financial Officer and Treasurer

## INHIBITOR THERAPEUTICS, INC.

### CERTIFICATION 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 Inhibitor Therapeutics, Inc. (the "Company") on Form10-Q for the period ending September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nicholas J. Virca, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(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 result of operations of the Company.

/s/ Nicholas J. Virca

Nicholas J. Virca President and Chief Executive Officer November 7, 2019

### INHIBITOR THERAPEUTICS, INC.

### CERTIFICATION 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 Inhibitor Therapeutics, Inc. (the "Company") on Form10-Q for the period ending September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Garrison J. Hasara, Chief Financial Officer, Treasurer, Chief Compliance Officer, and Secretary of the Company, certify, pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(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 result of operations of the Company.

/s/ Garrison J. Hasara Garrison J. Hasara Chief Financial Officer, Treasurer, Chief Compliance Officer, and Secretary November 7, 2019