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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 20, 2019 (August 19, 2019)

Inhibitor Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-13467	30-0793665
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4830 W. Kennedy Blvd., Suite 600
Tampa, Florida 33609
(813) 864-2559
(Address, including Zip Code and Telephone Number, including Area Code, of Principal Executive Offices)

HedgePath Pharmaceuticals, Inc.
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	**N/A**	**N/A**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year

Item 7.01 Regulation FD Disclosure

Item 8.01 Other Events

Effective August 20, 2019, HedgePath Pharmaceuticals, Inc. (the "Company") filed an amendment to its certificate of incorporation, as amended, with the Secretary of State of Delaware to change its corporate name from "HedgePath Pharmaceuticals, Inc." to "Inhibitor Therapeutics, Inc." (the "Name Change Amendment"). The Name Change Amendment was previously approved by the Company's board of directors and majority stockholder. The Name Change Amendment is filed as Exhibit 3.1 to this Current Report.

On August 19, 2019, the Company issued a press release regarding the change in its corporate name and also a change in the Company's trading symbol from "HPPI" to "INTI", effective with the opening of trading on August 20, 2019. A copy of such press release is filed as Exhibit 99.1 to this Current Report.

In addition, in light of the Company's corporate name and ticker symbol change, attached as Exhibit 99.2 to this Current Report is an updated form of corporate presentation that the Company expects to use during future presentations by Company management. The information in Exhibit 99.2 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Set forth below is a list of Exhibits included as part of this Current Report.

3.1	Certificate of Amendment to the Company's Certificate of Incorporation, dated August 20, 2019
99.1	Press release of the Company, dated August 19, 2019
99.2	Company corporate presentation

Cautionary Note on Forward-Looking Statements

This Current Report, the contents of Exhibits 99.1 and 99.2 to this Current Report, and any related statements of representatives and partners of the Company contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the anticipated benefits of the new corporate name and ticker symbol, as well as the actual results of the Company's anticipated future activities as described herein) may differ significantly from those set forth or implied in the forward-looking statements. These forward-looking statements involve numerous risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

SIGNATURES

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

Dated: August 20, 2019

INHIBITOR THERAPEUTICS, INC.

By: /s/ Nicholas J. Virca
Name: Nicholas J. Virca
Title: President and CEO

Exhibit 3.1

CERTIFICATE OF AMENDMENT TO THE CERTIFICATE OF INCORPORATION OF HEDGEPATH PHARMACEUTICALS, INC.

The undersigned, for the purposes of amending the Certificate of Incorporation of HedgePath Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "DGCL"), does hereby certify that:

FIRST: That the Board of Directors of the Corporation (the "Board") adopted a resolution proposing and declaring advisable the following amendment to Article FIRST of the Certificate of Incorporation of said Corporation:

"FIRST: The name of the corporation is Inhibitor Therapeutics, Inc. (the '**Corporation**"). The Corporation is to have perpetual existence.

SECOND: That in lieu of a meeting and vote of the stockholders of the Corporation (the 'Stockholders"), the Stockholders have given written consent to said amendments in accordance with the provisions of Section 228 of the DGCL, and written notice of the adoption of the amendments has been given as provided in Section 228 of the DGCL to every stockholder entitled to such notice.

THIRD: That the aforesaid amendments were duly adopted in accordance with the applicable provisions of Sections 242 and 228 of the DGCL.

FOURTH: The aforesaid amendment shall be effective as of 9:00 A.M. Eastern Standard time on August 20, 2019.

IN WITNESS WHEREOF, the Corporation has caused this Amendment to the Certificate of Incorporation of the Corporation to be duly executed by the undersigned this 14th day of August, 2019.

HEDGEPATH PHARMACEUTICALS, INC.

By: /s/ Nicholas J. Virca
Name: Nicholas J. Virca
Title: Chief Executive Officer

Exhibit 99.1

HedgePath Pharmaceuticals Announces Name Change to INHIBITOR Therapeutics, Inc. and Ticker Symbol Change to "INTI" Effective August 20, 2019

New Corporate Brand Exemplifies Multiple Near-term Growth Opportunities Involving Lead Technology, SUBA™- Itraconazole, Inhibiting the Hedgehog Signaling Pathway

INHIBITOR to Hold End of Phase 2 Meeting with FDA in Q4 2019 Prior to Filing IND for Phase 2b Clinical Trial of SUBA-Itraconazole in Prostate Cancer

INHIBITOR Renews and Expands Exclusive Worldwide Option Agreement with the University of Connecticut for Novel Compounds that Inhibit Upstream Targets of the Hedgehog Pathway

TAMPA, FL, August 19, 2019 – HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI), a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapeutics to inhibit the progression of cancerous and non-cancerous proliferation disorders, today announced plans to change its name to INHIBITOR Therapeutics as well as a change to the ticker symbol for common and preferred stock to "INTI" from "HPPI." Both the corporate name change and ticker symbol change are expected to be effective with the opening of trading on August 20, 2019.

In conjunction with the corporate name change, INHIBITOR will launch a new website (www.inhibitortx.com) to showcase INHIBITOR's vision and development strategy for SUBA-Itraconazole, a proprietary formulation of the FDA approved anti-fungal drug itraconazole designed to enable improved bioavailability compared to conventional itraconazole when used as an anti-cancer treatment, as well as novel compounds that inhibit upstream targets of the Hedgehog Pathway as treatments for cancer and non-cancerous proliferation disorders.

"Changing our name to INHIBITOR Therapeutics marks an important point of inflection for our company as we are now positioned to capitalize on several business and clinical development initiatives, offering potential catalysts for multiple value-building events during 2019 and 2020," stated Nicholas J. Virca, President and Chief Executive Officer of INHIBITOR. "In the near-term, following a pre-IND (Investigational New Drug) meeting with the Food and Drug Administration (FDA) in April this year, INHIBITOR has secured an End of Phase 2 Meeting (EOP2) with FDA scheduled for the fourth quarter of 2019 to finalize our clinical protocol and statistical analysis plan as we prepare to submit our IND application to study SUBA-Itraconazole in patients with late-stage prostate cancer. Upon IND clearance, we plan to initiate a multi-center, randomized, double-blind, placebo-controlled Phase 2b clinical trial in men with metastatic castrate-resistant prostate cancer (mCRPC) in 2020. Additionally, in 2020, we plan to hold discussions with the FDA to advance our Phase 2b clinical program to study SUBA-Itraconazole in patients with late-stage lung cancer."

Virca continued, "We are also excited to report the signing of a renewal, for an additional year, of an expanded, exclusive worldwide option agreement with the University of Connecticut to initiate pre-clinical testing in basal cell carcinoma using novel compounds (itraconazole analogues) designed to inhibit specific protein targets of the Hedgehog Pathway. We believe this technology has significant potential and could become a platform for targeting multiple cancerous and non-cancerous proliferation disorders."

About SUBA-Itraconazole

SUBA-Itraconazole is a patented formulation of itraconazole designed to enable improved absorption and significantly reduced variability compared to generic itraconazole. Research suggests that these properties offer the potential to provide reduced intra- and inter-patient variability, enable a more predictable clinical dose response, and reduce the active drug quantity required to deliver therapeutic levels into the bloodstream.

SUBA-Itraconazole is manufactured by Mayne Pharma under current Good Manufacturing Practice standards for INHIBITOR's use in clinical trials. An affiliate of Mayne Pharma is INHIBITOR's majority stockholder and the licensor of the SUBA-Itraconazole technology.

About University of Connecticut Itraconazole Analogues

The itraconazole analogues, which are being developed by Dr. M. Kyle Hadden, Associate Professor of Medicinal Chemistry, Department of Pharmaceutical Sciences at the University of Connecticut, have modifications to particular regions of the itraconazole scaffold. The patents and patent applications include compositions of matter claims covering the itraconazole analogues and method claims covering their use for the treatment of cancer. Data from Dr. Hadden's laboratory suggest that certain of these analogues maintain potent Hedgehog Pathway inhibition while exhibiting improved pharmacokinetic parameters and reduced off-target side effects sometimes associated with itraconazole. Initial testing efforts are focused on BCC tumor inhibition.

About INHIBITOR Therapeutics, Inc.

INHIBITOR Therapeutics, Inc. (OTCQB:INTI) (formerly known as HedgePath Pharmaceuticals, Inc. (OTCQB:HPPI)) is a pharmaceutical development company that discovers, develops and plans to commercialize innovative therapeutics to inhibit the progression of cancerous and non-cancerous proliferation disorders. HedgePath is the exclusive U.S. licensee of SUBA-Itraconazole in certain fields. Clinical studies have shown SUBA-Itraconazole to have greater bioavailability than generic itraconazole, a drug that has been approved by FDA for the treatment of certain fungal infections. The Hedgehog signaling pathway is a major regulator of cellular processes in vertebrates, including cell differentiation, tissue polarity and cell proliferation. Based on published research, INHIBITOR believes that inhibiting the Hedgehog pathway could delay or possibly prevent the development and progression of certain cancers, such as prostate cancer, in humans. Leveraging research undertaken by key investigators in the field, INHIBITOR is exploring the effectiveness of SUBA-Itraconazole as an anti-cancer agent and to pursue its potential commercialization. INHIBITOR is headquartered in Tampa, Florida. For more information, please visit www.inhibitortx.com.

Cautionary Note Regarding Forward Looking Statements

This press release and any statements of representatives and partners of INHIBITOR Therapeutics, Inc. (the "Company") related thereto contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the anticipated benefits of the new corporate name and ticker symbol, as well as the actual results of the Company's anticipated future activities as described herein) may differ significantly from those set forth or implied in the forward-looking statements. These forward-looking statements involve numerous risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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stilman@tiberend.com

Exhibit 99.2

INHIBITOR THERAPEUTICS

OTCQB:INTI

Corporate Presentation

August 2019

Cautionary Note on Forward-Looking Statements and Disclaimers

This presentation includes or incorporates by reference statements that constitute "forward-looking statements" within the meaning of the U.S. federal securities laws. These statements relate to future events or to our future performance, and involve significant known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied in these forward-looking statements. These statements include, but are not limited to, information or assumptions about our clinical development programs, our expenses, capital and other expenditures, our financing needs and plans, our capital structure, and management's plans, goals and objectives for future operations and growth. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "continue," "or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statement since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond our control and which could cause actual performance or results to differ materially from those expressed in or suggested by forward-looking statements.

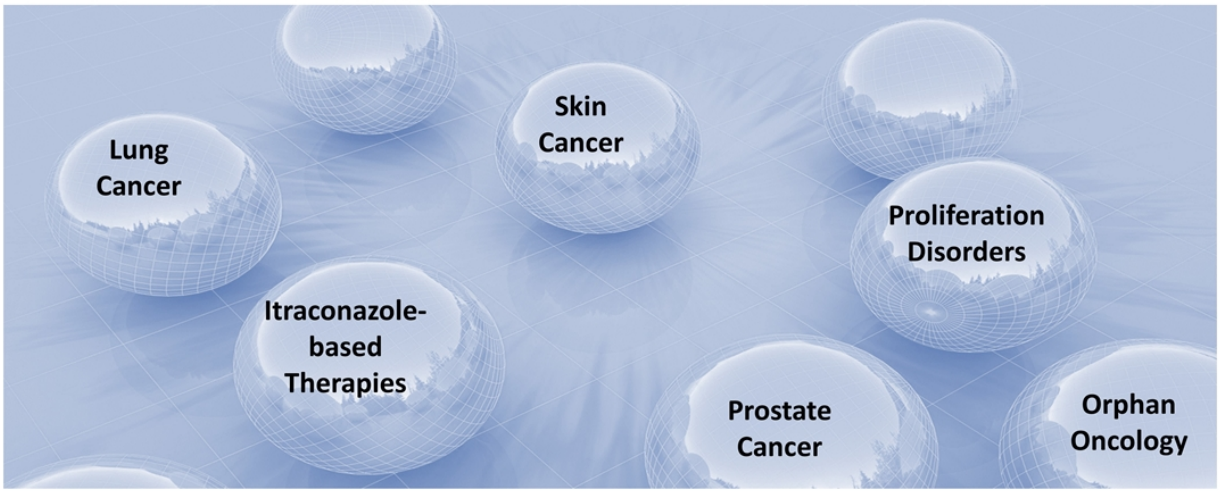
Important factors that could cause such differences include, but are not limited to: (i) risks and uncertainties associated with our research and development activities, including our anticipated clinical trials; (ii) our dependence on Mayne Pharma for the supply of our product candidate and key intellectual property; (iii) our ability to raise capital when needed; (iv) the timing of and our ability to achieve U.S. or international regulatory approvals for our product candidates; (v) our dependence on others to conduct clinical of, and to manufacture and market, our product candidates; (vi) our ability to gain market acceptance for our product candidates; (vii) our ability to maintain or protect the validity of patents and other intellectual property; (viii) our ability to secure registration for our current and future patent applications; and (ix) our ability to attract and retain key personnel.

Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material or even significant respects from those projected in these forward-looking statements. We do not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws. Peak sales estimates have been determined on the basis of market research and comparable product analysis, but no assurances can be given that such sales levels will be achieved, if at all.

This presentation does not constitute an offer or any securities for sale or solicitation of an offer to buy any securities, nor shall there be any sale of the securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or jurisdiction.

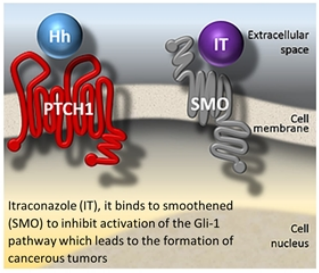
Mission Statement

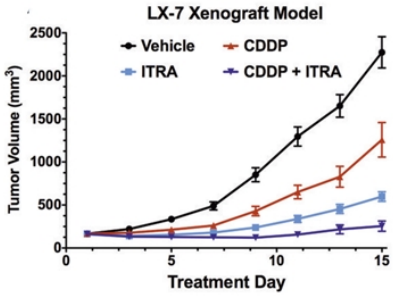
We are focused on the discovery, development and commercialization of innovative therapeutics to inhibit the progression of cancerous and non-cancerous proliferation disorders



Itraconazole: FDA-Approved Oral Anti-Fungal with Anti-Cancer Activity

- Itraconazole inhibits hedgehog signaling pathway via novel mechanism
  - Significant and safe history as an FDA-approved anti-fungal therapy
  - Demonstrated activity against multiple tumor types
  - *In vitro, in vivo* and physician-sponsored human studies
  - Well-tolerated daily oral therapy with limited side-effects at low doses
- Itraconazole has anti-angiogenic activity in addition to hedgehog pathway inhibition*
  - Inhibits endothelial cell proliferation, migration and tube formation
  - Associated with tumor hypoxia and reduced tumor vascularity in mouse xenograph studies
  - Tumor inhibition in non-small cell lung cancer (NSCLC) xenograft mice (with and without cisplatin)
  - Significant survival benefit in physician-sponsored lung cancer study**





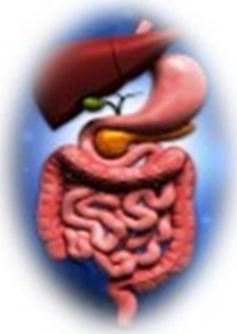
Vehicle – Control CDDP –Cisplatin
ITRA-Itraconazole

* Aftab, et al, Cancer Research Oct 2011

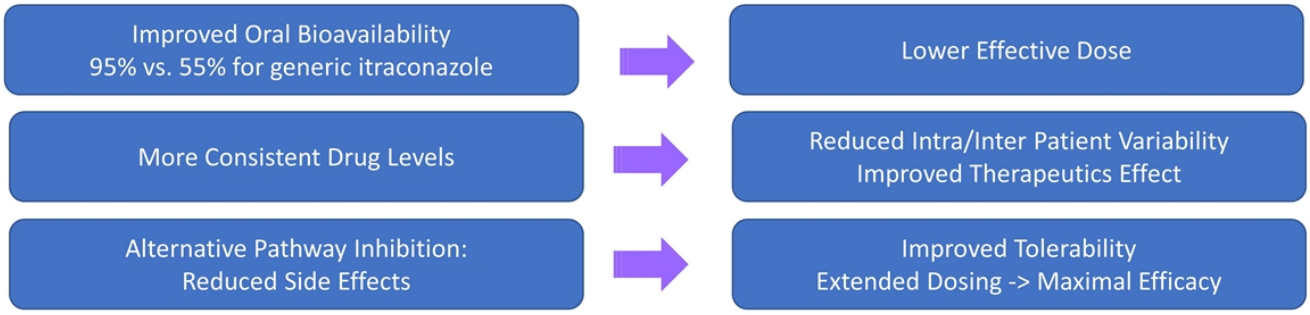
* * Johns Hopkins University, Rudin, et. al. *Journal of Thoracic Oncology,* May 2013

Challenges with Generic Itraconazole as an Anti-Cancer Therapy

- Itraconazole is poorly bioavailable (~55% when dosed orally)
- Inconsistent blood plasma levels from one dose to the next
- Inconsistent blood plasma levels between patients at the same dose
- Less predictable at higher doses required for anti-cancer therapies
- Requires meal intake plus the addition of acidic beverages
- Contraindicated for patients with achlorhydria (low acid stomach)
- Not to be used with proton pump inhibitors prescribed for acid reflux



SUBA-Itraconazole: Best-in-Class Potential



- SUBA = “Super Bioavailability”; polymer-based drug dispersion – intestinal release
- Fulfils unmet need for low toxicity, continuous hedgehog pathway inhibition or anti-angiogenic therapy
- Does not require the high doses necessary for generic itraconazole anti-cancer regimens
- Can be dosed in fed or fasted state, no concerns regarding acidity (achlorhydria or proton pump drugs)
- Patents cover composition of matter, manufacturing processes and indications
- INHIBITOR has exclusive U.S. rights from Mayna Pharma for SUBA-Itraconazole for certain cancers and non-cancerous proliferation disorders

Clinical Programs for SUBA-Itraconazole Anti-Cancer Therapies

Indication	Trial Design	Pre-Clinical	Phase 1	Phase 2	Phase 3	Next Milestone(s)
Basal Cell Carcinoma (BCC) in Basal Cell Carcinoma Syndrome (BCCNS)	SUBA-Itraconazole 1st line stand-alone therapy to delay or eliminate BCC lesion surgeries	505(b)(2) Regulatory Pathway Orphan Drug Designation				Mayne Pharma* to initiate FDA/EMA Global Ph 3 Registration trial in 2020
Late-Stage Prostate Cancer	SUBA-Itraconazole dosed with 1st or 2nd line dosed docetaxel - prednisone chemotherapy	505(b)(2) Regulatory Pathway				Launch Ph 2b US/EU clinical trial sites in 2020 (Potential Registration Trial)
Late-Stage Lung Cancer	SUBA-Itraconazole dosed with 2nd or 3rd line platinum chemotherapy	505(b)(2) Regulatory Pathway				File IND for Ph 2b trial by year-end 2020 (Potential Registration Trial & Fast Track Designation)
Basal Cell Carcinoma	Itraconazole Analogue efficacy/safety testing in Human BCC Xenograph Mice	BCC Animal Model				Initiate toxicology study based on efficacy safety signals from BCC mouse model – Q1 2020

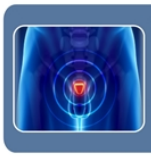
* Clinical work being funded and undertaken by Mayne Pharma; INHIBITOR to receive 9% royalty on sales if approved.

Clinical Experience Supports Pipeline Expansion

- Completed Ph 2b trial in Basal Cell Carcinoma Nevus Syndrome (BCCNS) in 38 patients across 5 U.S. sites
  - SUBA-Itraconazole decreased 57% of 477 BCC target lesions by 30% or more in size
  - Only 6 lesions required surgical excision across all 38 patients
  - 130 BCC target lesions (27%) completely disappeared
  - Demonstrated an improved toxicity profile (11% drop-out vs. 54% for vismodegib in Genentech BCCNS study)

- INHIBITOR management and clinical/regulatory teams demonstrated solid execution of first BCCNS trial
  - Confirmed 505(b)(2) regulatory pathway and awarded Orphan Drug Designation for BCCNS
- Mayne Pharma preparing to initiate Global Ph 3 trial in BCCNS based on INHIBITOR Ph 2b study results
  - Mayne pursuing regulatory guidance (FDA and EMA) to specify study endpoints for marketing approval
- Physician-sponsored trials also demonstrated proof of concept for itraconazole use in prostate and lung cancers
  - INHIBITOR will pursue 505(b)(2) pathway for SUBA-Itraconazole use with chemotherapy in those indications

Opportunity for SUBA-Itraconazole in Late-Stage Prostate Cancer



Second most common cause of cancer-related deaths in the U.S.

~30,000 men per year

First-line local and systemic therapies include surgery, radiation, and androgen deprivation therapy (ADT)

All patients with late-stage disease eventually become refractory to hormonal therapy (castrate-resistant)

Metastatic, Castrate-Resistant Prostate Cancer (mCRPC)

>23,000 Men (U.S.)

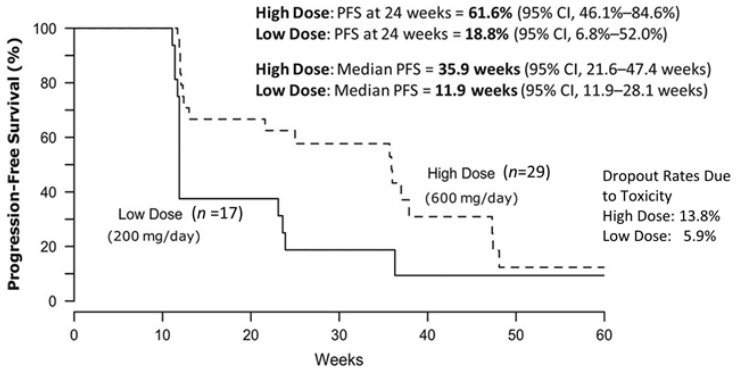
- Aberrant hedgehog signaling suggests a direct role in prostate cancer*
  - Promotes tumor formation and invasion
  - Contributes toward development of castrate-resistance and ADT failure

* Sing, et al, American Journal of Pathology 2014 , Susman, Antonarakis, Sep 2015 Cancers MDPI

Clinical Proof-of-Concept for Itraconazole in Late-Stage Prostate Cancer

- Randomized, multicenter Phase 2 study*
- Oral itraconazole (generic)
- Men with metastatic castrate-resistant prostate cancer

Progression-Free Survival (PFS)



* Johns Hopkins University, Antonarakis, *et. al*, *The Oncologist,* February 2013

90% of men who achieved therapeutic levels of itraconazole had **dramatic reductions in PSA** which correlated significantly with **Progression-Free Survival***

*Data on file, INHIBITOR Therapeutics, Inc. - U.S. Patent 9,192,609

Clinical Strategy for SUBA-Itraconazole in Late-Stage Prostate Cancer

Phase 2b PREDICT* Trial Design: Randomized, controlled, multi-center clinical trial

- Oral SUBA-Itraconazole in combination with standard of care docetaxel-prednisone chemotherapy
- Objective: Evaluate the ability to delay disease progression in high-risk men with metastatic castration-resistant prostate cancer (mCRPC)

April 2019 : Face-to-Face Pre-IND FDA Meeting Agreements

- Primary endpoint of rPFS (radiographic progression-free survival)
- Potential for registration based on End of Phase 2 (EOP2) Protocol and Statistical Analysis Plan
- Allowed to leverage itraconazole and SUBA-Itraconazole safety data
- Confirmed 505(b)(2) regulatory pathway; Right of reference to Mayne Pharma Drug Master File

2019 Upcoming Milestones

- Q4: EoP2 Meeting (potential FDA signoff on registrational design); IND clearance to proceed with Ph 2b multi-center, double-blind, randomized placebo-controlled trial

* Prostate Response Evaluating Docetaxel Itraconazole Combination Therapy

Opportunity for SUBA-Itraconazole in Late-Stage Lung Cancer

Lung cancer is the leading cause of cancer-related deaths in the U.S.: 160,000 / year

> colon, breast & prostate combined

85% are non-small cell lung cancer (NSCLC)

~75,000 newly diagnosed at Stage 4 / year

Significant unmet need for patients with late-stage disease requiring chemotherapy

Only ~50% of patients with advanced, non-squamous NSCLC are candidates for targeted chemotherapy drugs or immunotherapy*

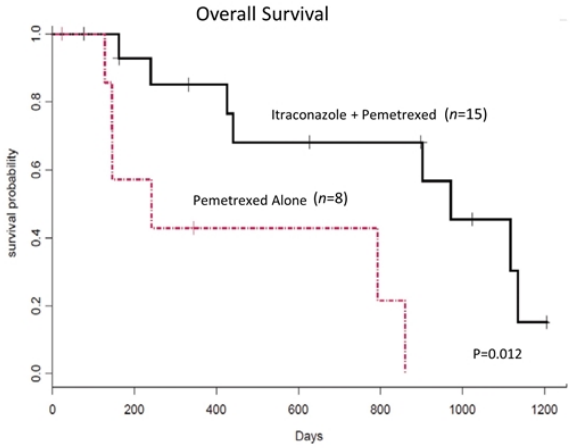
~45,000 patients per year (U.S.)

- Itraconazole has anti-angiogenic mechanisms in addition to hedgehog pathway inhibition
  - Inhibits endothelial cell proliferation, migration, and tube formation
  - Associated with tumor hypoxia and reduced tumor vascularity in mouse xenograft studies

* Johns Hopkins University, Rudin, et. al. *Journal of Thoracic Oncology,* May 2013; American Cancer Society 2018

Clinical Proof-of-Concept for Itraconazole in Late-Stage Lung Cancer

- Randomized, controlled Phase 2 study of oral itraconazole (generic)
- Patients with metastatic non-squamous non-small cell lung cancer (NS NSCLC)
- Two-arm study: Combination with standard dose of second-line Pemetrexed



Johns Hopkins University, Rudin, et. al. *Journal of Thoracic Oncology*, May 2013

Improved Median Survival from 8 months to 32 months
Well tolerated with Grade 3 toxicity related to Pemetrexed (5 patients total)

SUBA-Itraconazole oral therapy may extend survival in patients with unmet need

Clinical Strategy for SUBA-Itraconazole in Late-Stage Lung Cancer

Phase 2b Trial Design: Randomized, Controlled, Multi-Center

- Oral SUBA-Itraconazole in combination with standard of care chemotherapy
- Objective: Evaluate the ability to delay disease progression in patients with advanced non-squamous non-small cell lung cancer

Upcoming Milestones

- 2020: IND clearance for Phase 2b study via 505(b)(2) pathway in NS NSCLC
- Pursue FDA Fast Track and/or Breakthrough Therapy Designation status based on progression-free survival benefit in patients with late-stage NS NSCLC

Preclinical Strategy for Itraconazole Analogues (IAs)* in Basal Cell Carcinoma (BCC)

Pre-clinical Trial Design: Basal Cell Carcinoma Mouse Model

- Oral IA dosing (gavage fed mouse model with human BCC xenographs)
- Objective: Evaluate the efficacy and safety of IA against human BCC

Upcoming Milestones

- Q4 2019: Evaluate BCC mouse model efficacy and safety for IA dosing
- Q1 2020: Initiate toxicology studies assuming efficacy signals in human BCC mouse study

* *Itraconazole Analogues (IAs) are subject to a worldwide exclusive option agreement with The University of Connecticut*

Estimated Market Opportunity in Advanced Cancers and BCCNS

- Total available markets for Itraconazole* therapies upon potential approvals

Indication	Patients (U.S.)	Positioning	Monthly Cost	Peak Sales Estimate**
BCCNS *SUBA-Itraconazole*	~10,000	1st line therapy to delay surgeries	$4,000 - $5,000	$300 million***
Late-Stage Prostate Cancer *SUBA-Itraconazole*	~23,000	2nd line with chemotherapy	$4,000 - $5,000	$215 million
Late-Stage Lung Cancer *SUBA-Itraconazole*	~45,000	2nd- 3rd line with chemotherapy	$4,000 - $5,000	$270 million
BCC pre-treatment prior to surgical excision *Itraconazole Analogue*	~65,000	Adjunct therapy to BCC surgery	$4,000 -$5,000	$600 million

* Itraconazole therapies include SUBA-Itraconazole Oral Capsules licensed from Mayne Pharma and Itraconazole Analogues optioned from the University of Connecticut
** INHIBITOR projected peak sales based upon number of patients, length of therapy for *SUBA-Itraconazole* use in conjunction with select chemotherapy regimens for Prostate, Lung cancers and BCCNS and length of therapy for *Itraconazole Analogue* for BCC adjunct therapy
*** INHIBITOR to receive 9% sales royalty from Mayne Pharma

Poised for Growth

Collaboration and funding agreement with Mayne Pharma	• Transferred development to Mayne Pharma to launch Global Phase 3 for BCCNS indication (9% royalty on future sales) • Up to $5 million* (non-dilutive funding) for clinical development of SUBA-Itraconazole in late-stage prostate and lung cancers
Strategically acquire/license additional drug candidates	• Exclusive option agreement with University of Connecticut evaluating next-generation itraconazole analogues with lower toxicities and more potent anti-cancer properties (*in vivo* BCC animal studies) • Exploring innovative therapeutics that address unmet needs and orphan oncology indications
Exploring potential up-list to NASDAQ	• Enhance visibility and attain more appropriate market valuation in line with de-risked pipeline in late-stage cancer indications • Achieve greater liquidity and access to capital from institutional and retail biotech investors

* $3 Million to INHIBITOR as of July 1, 2019

Management Team

Nicholas Virca, President & Chief Executive Officer

- 30 years in Human Therapeutics and Diagnostics (20 years at C Level)
- Co-founder HedgePath, Adventrx Pharmaceuticals, Diametrix Detectors, and Damon Biotech

Garrison Hasara, CPA, Chief Financial Officer

- 20 years in Accounting and Finance (including biotech PIPEs and S1 – S3 financings)
- Previous senior management positions in finance with Accentia Pharmaceuticals, Automotive Service Centers, and Kforce

Amy McCord, Ph.D., RAC, Vice President, Regulatory Affairs *

- 10 years Regulatory & Scientific Research (Ph.D. in Biomedical Sciences-USF)
- Previous senior management positions with DSI, Inc., Cardinal Health, Biovest International, Accentia Biopharmaceuticals, and Moffitt Cancer Center USF

*Consultant contact

Board of Directors

Mark Watson, CPA - Chairman

- 40 years in Public Accounting and Auditing in healthcare and life sciences
- Retired Deloitte Touche Tohmatsu, serves on the boards of Sykes Enterprise and Biotechnology Sciences International Member of American Institute of Public Accountants

Robert D. Martin - Director

- 30 years experience in Financial Consulting and Operations
- Previous experience with The Interlochen Group, Tandy Brands Accessories, Intezyne, and Russell Corporation

Stefan J. Cross – Director

- 20 years experience in Pharmaceuticals
- Current and previous management positions with Mayne Pharma as President of US Subsidiary of Mayne, VP Business Development of non-US operations and former Head of Marketing Asia Pacific for Hospira

Dana R. Ono, Ph.D. – Director

- 35 years C-level experience in Public and Private Life Science companies and Venture Capital
- Co-founder VIMAC Media Fund, founder of several biotech companies in drug discovery and development; founder of the Massachusetts Biotechnology Council and on the board of Marine Biological Laboratory Woods Hole, Massachusetts

De-Risked, Clinically Advanced Pharmaceutical Development Company

Itraconazole is **FDA-approved** (anti-fungal) with known anti-cancer properties

- Targets the well-validated "hedgehog" signaling pathway
- Best-in-class potential
- Accelerated 505(b)(2) regulatory pathway

Advancing **proprietary oral drug formulations** of itraconazole

- "SUBA"-Itraconazole
  - Proven bioavailability, safety and anti-tumor efficacy in Phase 2b
- Significantly improved tolerability vs. approved products that target same pathway

Positive Phase 2 data in late-stage cancer studies

- Clinical proof-of-concept demonstrated in physician-sponsored Phase 2 Trials:
  - PFS/OS benefits for generic itraconazole
- Completed Phase 2b of SUBA-itraconazole in BCCNS; Mayne Pharma initiating global Phase 3 trial

Poised for **Significant Growth**

- Advancing Pipeline: Planning to initiate Phase 2b trials in late-stage prostate and lung cancers
- Pipeline Expansion: Itraconazole analogue technology & orphan oncology opportunities
- Exploring potential up-list to NASDAQ

Contact Us

For Additional Information:

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