

### COMMON STOCK plus CZ48 DRUG REVENUE INTERESTS

Maximum Offering: USD \$5,000,000

Target Offering: USD \$10,000

Minimum Subscription: USD \$1,000

# THIS OFFERING STATEMENT IS AN EXHIBIT TO, IS A PART OF, AND SHOULD BE READ IN CONJUNCTION WITH, THE COMPANY'S FORM C AS FILED WITH THE U.S. SECURITIES AND EXCHANGE COMMISSION WHICH FORM C IS INCORPORATED INTO THIS COVER PAGE BY REFERENCE AS IF FULLY SET FORTH.

# FOR MORE INFORMATION, PLEASE CONTACT THE COMPANY'S DESIGNATED REGISTERED FUNDING PORTAL OR DESIGNATED INTERMEDIARY:

Silicon Prairie Portal & Exchange, LLC

The effective date of this Offering Statement is April 19, 2022

A crowdfunding investment involves risk. You should not invest any funds in this offering unless you can afford to lose your entire investment.

In making an investment decision, investors must rely on their own examination of the Issuer and the terms of the offering, including the merits and risks involved. These securities have not been recommended or approved by any federal or state securities commission or regulatory authority. Furthermore, these authorities have not passed upon the accuracy or adequacy of this document.

The U.S. Securities and Exchange Commission does not pass upon the merits of any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering document or literature.

These securities are offered under an exemption from registration; however, the U.S. Securities and Exchange Commission has not made an independent determination that these securities are exempt from registration.

Cao Pharmaceuticals Inc., a Texas corporation ("we", "us", "our", the "Issuer", or the "Company"), is offering these securities pursuant to available exemptions from registration claimed under Section 4(a)(6) of the Securities Act of 1933, as amended (the "Securities Act"), and pursuant to Regulation Crowdfunding promulgated by the U.S. Securities and Exchange Commission (the "SEC" or "Commission") as authorized under Title III of the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act").

Accordingly, the Company will file a report with the Commission annually and post the report on its website, no later than 120 days after the end of each fiscal year covered by the report.

The Company may terminate its reporting obligations in the future in accordance with Rule 202(b) of Regulation Crowdfunding in the event:

- (1) the Company is required to file reports under Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended (the "Exchange Act");
- (2) the Company has filed, since its most recent sale of securities pursuant to Regulation Crowdfunding, at least one annual report pursuant to Regulation Crowdfunding and has fewer than 300 holders of record;

This cover page is continued on the following pages

- (3) the Company has filed, since its most recent sale of securities pursuant to Regulation Crowdfunding, the annual reports required pursuant to Regulation Crowdfunding for at least the three most recent years and has total assets that do not exceed USD \$10,000,000;
- (4) the Company or another party repurchases all of the Securities issued in reliance on Section 4(a)(6) of the Securities Act including any payment in full of debt securities or any complete redemption of redeemable securities; or
- (5) the Company liquidates or dissolves its business in accordance with state law.

The Company's filings and reports pursuant to Regulation Crowdfunding may be viewed online at www.sec.gov.

# IMPORTANT NOTICES ABOUT THE INFORMATION PRESENTED IN THIS OFFERING STATEMENT

This document is our Offering Statement (this "Offering Statement") to be presented to potential investors as part of the Company's Form C as filed with the Commission pursuant to Section 4(a)(6) of the Securities Act and Regulation Crowdfunding. This Offering Statement is not to be used for any other purpose or in any other context. This Offering Statement has been prepared for the sole purpose of providing certain information regarding an investment in the Securities of the Company by investors who qualify under Regulation Crowdfunding. It does not purport to be complete and is subject to change, correction, amendment and/or supplementation.

THIS OFFERING OF SECURITIES IS BEING MADE IN RELIANCE UPON ONE OR MORE EXEMPTIONS FROM REGISTRATION UNDER THE U.S. SECURITIES ACT AND U.S. STATE SECURITIES LAWS. THIS OFFERING STATEMENT DOES NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY IN ANY STATE OR OTHER JURISDICTION WHERE IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION IN SUCH JURISDICTION AND MAY NOT BE USED IN ANY STATE OR OTHER JURISDICTION IN WHICH AN OFFER OR SOLICITATION OF SECURITIES IS NOT AUTHORIZED.

STATEMENTS IN THIS OFFERING STATEMENT ARE MADE AS OF THE DATE HEREOF UNLESS STATED OTHERWISE, AND NEITHER DELIVERY OF THIS OFFERING STATEMENT AT ANY TIME, NOR ANY SALES HEREUNDER, SHALL UNDER ANY CIRCUMSTANCES CREATE AN IMPLICATION THAT THE INFORMATION CONTAINED HEREIN IS CORRECT AS OF ANY TIME SUBSEQUENT TO THE DATE HEREOF OR THAT THERE HAS BEEN NO CHANGE IN THE BUSINESS, FINANCIAL CONDITION OR PROSPECTS OF THE COMPANY SINCE THE DATE HEREOF AND/OR THE DATES REFERRED TO HEREIN. IN ADDITION, THE COMPANY IS UNDER NO OBLIGATION TO UPDATE THE INFORMATION PRESENTED HEREIN.

PROSPECTIVE INVESTORS SHOULD NOT CONSTRUE THE CONTENTS OF THIS OFFERING STATEMENT AS LEGAL, TAX OR INVESTMENT ADVICE. LEGAL COUNSEL, ACCOUNTANTS OR INVESTMENT ADVISORS HAVE NOT BEEN ENGAGED BY THE COMPANY OR ITS AFFILIATES ON BEHALF OF PROSPECTIVE INVESTORS. ACCORDINGLY, EACH PROSPECTIVE INVESTOR SHOULD CONSULT THEIR OWN LEGAL COUNSEL, ACCOUNTANT OR INVESTMENT ADVISOR AS TO LEGAL, TAX AND RELATED MATTERS CONCERNING THEIR CONTEMPLATED INVESTMENT IN THE COMPANY'S SECURITIES. IN PROVIDING THIS OFFERING STATEMENT, THE COMPANY IS NOT MAKING ANY REPRESENTATION TO ANY OFFEREE OR PURCHASER OF THESE SECURITIES REGARDING THE LEGALITY OR SUITABILITY OF AN INVESTMENT THEREIN BY SUCH OFFEREE OR PURCHASER UNDER APPLICABLE LAWS. IN MAKING AN INVESTMENT DECISION, INVESTORS MUST RELY ON THEIR OWN EXAMINATION OF THE COMPANY AND THE TERMS OF THE OFFERING INCLUDING THE MERITS AND RISKS INVOLVED.

IRS Circular 230 Disclosure: To ensure compliance with U.S. Treasury Department Circular 230, Investors in the Securities are hereby notified that: (a) any discussion of U.S. Federal tax issues in this document is not intended or written by the Company to be relied upon, and cannot be relied upon by Investors in the Securities, for the purpose of avoiding penalties that may be imposed on Investors in the Securities under the U.S. Internal Revenue Code (the "Code"); (b) such discussion is written in connection with the promotion or marketing of the transactions or matters addressed herein by the Company; and (c) Investors in the Securities should seek advice based on their particular circumstances from their own independent tax advisors.

This Offering Statement amends and restates all prior versions, if any, through the latest date shown on the cover page hereof.

By receiving this Offering Statement you agree not to transmit, reproduce or make this Offering Statement or any related exhibits or documents available to any other person or entity. Your breach of this condition may cause the Company to incur actual damages of an indeterminable amount, subjecting you to potential legal liability.

Any clerical mistakes or errors in this Offering Statement are ministerial in nature and are not a material factual misrepresentation or a material omission of fact.

As there is a relatively low minimum target offering threshold in this Offering, initial or earlier investors may bear a greater and disproportionate share of the risk factors set forth in this Offering Statement than investors who invest later or when the Company is better capitalized (See "Risk Factors").

We reserve the right to withdraw this Offering at any time and for any or no reason without notice.

We also reserve the right to issue securities of any kind at any time on terms other than the terms set forth in the Offering Statement, including, but not limited to, entering into one or more side-letters materially adjusting such terms.

This Offering Statement does not constitute an offer in any jurisdiction or to any person to whom it is unlawful to make such an offer in such jurisdiction.

An offer may be made only through the Company's registered funding portal and/or other designated intermediary and must be accompanied by a copy of this Offering Statement including Form C and all Exhibits. No other person has been authorized to give you any other information or make any representations other than those contained in this Offering Statement. If you receive other information, do not rely on it.

Our affairs may have changed materially since the date on the cover of this Offering Statement. Neither delivery of this Offering Statement nor any transactions made hereunder shall, under any circumstances, create an implication that there has been no material change in our affairs since that date.

You and/or your advisors and representatives may ask questions of, and receive answers from, our Management concerning the terms and conditions of this Offering Statement as well as our overall objectives. We also will endeavor to provide you with any additional information, to the extent we possess such information or can acquire it without unreasonable effort or expense, necessary to substantiate the information set forth in this Offering Statement.

Securities acquired through this Offering Statement may not be transferred without the express written permission of the Company or in the absence of an effective registration statement unless the prospective transferee establishes, to the satisfaction of the Company, that an exemption from registration is available. Any certificates evidencing ownership of securities offered hereby shall bear a restrictive legend to this effect.

The securities described herein should be considered a non-liquid, speculative investment. (See "Risk Factors").

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# EXHIBITS:

A: COPY OF ARTICLES OF INCORPORATION

B: COPY OF BYLAWS

C: FINANCIAL INFORMATION

D: FORM OF STOCK PURCHASE AND CZ48 DRUG REVENUE AGREEMENT

#### THE COMPANY

The name of the Issuer of the Securities described in this Offering Statement is Cao Pharmaceuticals Inc., a Texas corporation (referred to herein as "we", "us", "our", the "Issuer", or the "Company").

#### ELIGIBILITY

The Company is organized under, and subject to, the laws of a State or territory of the United States or the District of Columbia.

The Company is not subject to the requirement to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

The Company is not an investment company registered or required to be registered under the Investment Company Act of 1940, as amended.

The Company is not ineligible to rely on the exemption available under Section 4(a)(6) of the Securities Act as a result of a disqualification specified in Rule 503(a) of Regulation Crowdfunding. (For more information about these disqualifications, please see the "Legal Proceedings" section of this Offering Statement).

The Company has filed with the Commission and provided to investors, to the extent required, the ongoing annual reports required by Regulation Crowdfunding during the two years immediately preceding the filing of this Offering Statement (or for such shorter period that the Issuer was required to file such reports).

The Company is not a development stage company that (a) has no specific business plan, or (b) has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies.

To our knowledge and belief, neither the Company nor any of its predecessors have previously failed to comply with the ongoing reporting requirements of Rule 202 of Regulation Crowdfunding.

# **COMPANY MANAGEMENT**

We are a corporation governed by a Board of Directors (the "Board") and managed on a day-to-day basis by officers appointed by the Board. Directors and officers serve until their successors have been duly chosen and elected. By way of majority vote or written consent, our Common Shareholders may remove the Board with or without cause.

Our Board may fix the compensation of all Company officers. Pursuant to this authority, the Board may, by resolution, provide for Directors to be paid their expenses, if any, for attendance at each meeting of the Board, and may be paid a stated salary or a fixed sum as a Director for attendance at each meeting of the Board. No such payment shall preclude any Director from also serving as an officer of the Company or in any other capacity and receiving compensation therefrom. The Board may adopt incentive compensation plans in the form of Shares, stock options, warrants, etc., in the future for our Management, directors, officers, consultants, advisors, employees or others.

Officers appointed by the Board shall conduct the operation and management of the Company's business on a day-to-day basis on such terms and for such compensation as the Board shall determine. No officer is prevented from also holding a position as a Director concurrently.

The biographies of certain of our key officers, directors, or other key personnel, consultants or advisors, are set forth below. It does not purport to be complete and is subject to change. A complete and current list of our officers, directors, or other key personnel, consultants or advisors is available anytime upon request.

#### Zhisong Cao, Ph.D., CEO and Chief Chemist

Having served as the Company's CEO for the past three (3) years prior the date of this Offering Statement, Dr. Cao has over twenty years of experience in CPT chemistry and is inventor and co-holder of 17 CPT related patents and licensing of CPT compounds. Prior to founding Cao Pharmaceuticals, he served as the Associate Laboratory Director and Chief Chemist for the Stehlin Foundation. In this capacity he was responsible for all Chemistry R&D, and strategic direction of drug development, patenting and licensing. In his twenty years of being solely involved in CPT drugs, he has synthesized hundreds of CPT drugs using thousands of drug intermediates. This rare amount of knowledge provides Cao Pharmaceuticals Inc. a distinct advantage in the design and synthesis of pipeline candidates of these drugs targeted for specific pharmacological activity.

#### Yang Wang, Ph.D., Chief Pharmacologist

Prior to joining Cao Pharmaceuticals, Dr. Wang had over twenty years of experience in CPT (camptothecin) related drug development as a Research Scientist at the Stehlin Foundation for Cancer Research. At Cao Pharmaceuticals, where she has worked during the past 3 years prior to the date of this Offering Statement, she oversees both the pre-clinical testing and formulation development of the pipeline drugs, and the clinical pharmacokinetics, pharmacodynamics, and biomodelling studies of the phase I clinical trial of CZ48, a camptothecin derivative.

#### **Chris Wood, VP of Investor Relations**

Chris Wood heads the Company's Investor Relations desk with over 30 years of experience of finance, accounting, information technology, management, and business ownership experience. He currently (and, for the past 3 years prior to the date of this Offering Statement, has done so) coordinates investor relations for the Company and helps secure funding with a view towards completing the Company's CZ48 Phase I FDA trial and towards beginning the FDA Phase II trials.

\* \* \* \* \*

We intend to recruit additional officers, managers, consultants, advisors, and other key personnel as we continue to grow. Consequently, the above list is subject to change and supplementation from time to time without notice.

#### PRINCIPAL SECURITY HOLDERS

The following table provides the name and ownership level of each person, as of the most recent practicable date, who is the beneficial owner of 20 percent or more of the Issuer's outstanding voting equity securities, calculated on the basis of voting power:

Name of Beneficial Owner	Title of Class	Amount and Nature of Beneficial Ownership (7)	Percentage of Ownership (1)(2)(3)(4)(5)(7)
Zhisong Cao, Ph.D., CEO, Director, and Chief Chemist, and spouse Yangping (6)	Common	10,000	84.94%
NMT Pharmaceuticals PTE LTD	Common	1,760	14.95%

#### Cao Pharmaceuticals Inc.

#### REGULATION CROWDFUNDING OFFERING STATEMENT

Other Shareholders (8)	Common	13	0.11%

#### FOOTNOTES TO TABLE:

(1)	Beneficial ownership is determined in accordance with the rules of the U.S. Securities and Exchange
	Commission (the "SEC") and generally includes voting or investment power with respect to securities.
(2)	Subject to rounding, the percentage is based on an estimated total of 11,773 Common Shares outstanding on
	a fully-diluted basis as of the date of this Offering Statement. See "Capitalization and Indebtedness".
(3)	Subject to dilution or change upon the issuance of new Shares or Options (see "Dilution" and "Capitalization
	and Indebtedness").
(4)	See "Compensation".
(5)	The balance of the Company's outstanding Shares are held by and among approximately 12 shareholders
	who purchased Shares under an exemption from registration (Section 4(a)(2)) prior to this Offering.
(6)	See "Management and Key Personnel".
(7)	Actual numbers and percentages may materially vary. See Schedule A of the attached Stock Purchase and
	CZ48 Drug Revenue Agreement in the Exhibit Section of this Offering Statement.
(8)	Comprised of 17 shareholders of record, some of whom may be affiliates of the Company or of our
	management.

## **BUSINESS AND ANTICIPATED BUSINESS PLAN**

#### **Our Company**

Cao Pharmaceuticals Inc., a Texas corporation ("we", "our", "us", "CPI", or the "Company"), is an early clinical stage oncology drug development company. Our principal place of business is located at 17490 Hwy. 3, Suite B200, Webster, Texas 77598 USA. Our main telephone number is 281-253-3812. General e-mail inquiries may be sent to chrisw@caopharmaceuticals.com. Our Objectives

We are seeking to develop one or more effective prescription drugs from a natural plant-based extract with relatively low or readily manageable toxicity with a view towards the future treatment of one or more solid tumors in the human body (e.g., colon, lung, breast, prostrate, melanoma, sarcoma, pancreatic, liver, etc., and/or lymphoma). We are also seeking to implement shorter development timeframes compared to traditional chemotherapies. We have already conducted a Phase I clinical trial with our lead drug "CZ48". This Phase I clinical trial went well and the most tolerated dose (MTD) was determined, we will seek to enter into Phase II trials and beyond with a view towards market clearance of CZ48 by the U.S. Food and Drug Administration (FDA) for medical treatment. There can be no assurance these objectives will be achieved.

#### Background and Overview: Camptothecin (CPT)

Camptothecin (CPT) based drugs, derived from a plant extract from the tree Camptotheca acuminata, were discovered in the mid-1960s and shown to have very promising potential as anticancer drugs. Their mechanism of action inhibits the activity of Topoisomerase I, an enzyme necessary for DNA replication in cell division, and leads to cell death by apoptosis. The significance of these compounds was quickly recognized and as a result much work has been done in an attempt to tap their vast potential. The team at Cao Pharmaceuticals have been at the forefront of CPT based drug design. Our view is that the potential of these drugs has just begun to be unlocked. This view stems not only from our knowledge and experience in designing and studying new CPT based drugs in the laboratory, but also from seeing first-hand activity in human use.

CPT was discovered during a study conducted by the NIH in testing over 1,000 natural plant extracts gathered from around the world. Of all of these natural extracts, only one had preferential killing of human cancer cells while not harming normal cells. The next step was to study these drugs in humans. Several clinical trials were performed with CPT based drugs. The first trial was with

plain CPT (the natural extract). Fifty patients were treated with one complete response (CR) in a Stage 4 lymphoma patient. In the laboratory several new derivatives were designed which demonstrated improved efficacy and lower toxicity. One of these compounds was 9-NitroCamptothecin (9NC). This derivative was then studied in a Phase I trial and there was activity seen in pancreatic cancer. From these results a Phase II trial was initiated treating patients with pancreatic cancer. Even with the best medical care available the average survival is around 6 months.

106 patients with advanced pancreatic cancer were treated with survival as an endpoint. Of the evaluable patients approximately one third had no difference in survival, one third lived past 12 months and another third lived past 18 months, with 11 of these surviving 24 months with 2 long term cures. As good as these results were there was a tremendous disconnect between the near cure in treating human cancers in the nude mouse model and these clinical results.

From basic laboratory research, it was determined that the last ring in the CPT drug must remain closed in the lactone form to be active. When the ring opens forming the carboxylate the compound loses over 90% of its activity. It was determined that the reason for the disparity between the mouse data and the pancreatic trial outcome was an albumin species difference between mouse and man. Albumin is a natural protein component of the blood and accounts for over 50% of blood protein. In the mouse blood there is a high concentration of active drug for several hours. Unfortunately Human Serum Albumin (HSA) has an avid affinity to bind to the inactive form of the drug (carboxylate) and causes rapid conversion of the active form of the drug to the inactive form. In humans in just one hour there is less than 10% active drug circulating in the blood. The encouraging news was that the positive outcomes in the Phase II pancreatic study were obtained with just this small fraction of active drug.

#### **CZ48** Overview

Our lead drug candidate "CZ48" has been synthesized to circumvent this binding to HSA, yet retain a high degree of anti-cancer activity. In vitro studies show that when this drug is incubated with Human Serum Albumin (HSA), there is more than a tenfold increase in active drug compared to 9NC. This increase in drug availability should translate into an even higher degree of efficacy. This new drug is currently in a FDA approved Phase I clinical trial.

We believe CZ48 is an improved form of the drug 9-NitroCamptothecin (9NC). In clinical trials of 9NC, even with very low blood levels of active drug (< 5%), outcomes showed significant activity and improved survival in patients with advanced pancreatic cancer. CZ48 has been designed to significantly improve blood levels compared to 9NC, yet retain this high degree of anti-cancer activity. In vitro studies show that when CZ48 is incubated with Human Serum Albumin (HSA), blood levels of active drug are increased more than tenfold compared to 9NC. This increase in drug availability should translate into an even higher degree of efficacy.

The Phase I clinical trial of CZ48 was comprised of three dosing steps, dose escalation, maximum tolerated dose (MTD) confirmation, and MTD re-confirmation. patient toxicity had been very limited. This is exciting news for us as this was one of the design goals of CZ48. This Phase I trial was completed by May 31, 2021. The Phase II trials to evaluate efficacy are schedule to start in Q1 of 2022.

We believe some of the advantages of CZ48 include:

- Oral Administration (i.v. formulations will be available for certain indications)
- Passes the blood brain barrier
- Data suggests killing of cancer stem cells
- Limited and Manageable toxicity
- Good efficacy
- Biomarker development to identify patients sensitive to specific CPT drugs

NOTE: DUE TO THE PROPRIETARY NATURE OF THE COMPANY'S WORK, THE COMPANY HAS ELECTED TO PLACE ONLY SELECTED DUE DILIGENCE INFORMATION IN THIS OFFERING STATEMENT. YOU ARE ENCOURAGED TO ARRANGE A MEETING WITH THE COMPANY'S MANAGEMENT TO REVIEW FURTHER DETAILS REGARDING OUR CZ48 DRUG AND/OR OTHERS AT THE OFFICES OF THE COMPANY. IN SOME CASES, A NON-DISCLOSURE / NON-CIRCUMVENTION AGREEMENT MUST BE SIGNED. For more information regarding the Company and our plans for the future, please contact us:

> Cao Pharmaceuticals Inc. 17490 Hwy. 3, Suite B200 Webster, Texas 77598 USA Telephone: 281-253-3891 E-mail: chrisw@caopharmaceuticals.com

#### **RISK FACTORS**

A crowdfunding investment involves risk. You should not invest any funds in this offering unless you can afford to lose your entire investment.

In making an investment decision, investors must rely on their own examination of the Issuer and the terms of the offering, including the merits and risks involved. These securities have not been recommended or approved by any federal or state securities commission or regulatory authority. Furthermore, these authorities have not passed upon the accuracy or adequacy of this document.

The U.S. Securities and Exchange Commission does not pass upon the merits of any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering document or literature.

These securities are offered under an exemption from registration; however, the U.S. Securities and Exchange Commission has not made an independent determination that these securities are exempt from registration.

The securities described in this Offering Statement entail certain risks that investors should consider before making decision to accept the terms of this Offering. There can be no assurance that any rate of return or other investment objectives will be realized or that there will be any return of capital. While no list of risk factors can be conceived to illuminate all possible risks, you should consider the following risk factors among others in making an investment decision:

### GENERAL RISK CONSIDERATIONS

#### The securities being offered are speculative and involve high risk

The Securities being offered via this Offering Statement should be considered speculative involving a high degree of risk. Therefore, you should thoroughly consider all of the risk factors discussed herein. You should understand that it is possible that you could lose your entire capital contribution or investment if the Company is ultimately not successful. You should not subscribe if you are unwilling to accept the risks associated with the Company and/or its Affiliates.

#### This Offering Statement includes forward-looking statements

This Offering Statement includes many forward-looking statements. These forward-looking statements are subject to risks, uncertainties and assumptions, including, among other things:

- The actions of our competitors;
- Successful implementation of our objectives;

- Resonance for our products in the marketplace;
- Effectiveness of the legal, economic, and business strategies employed by us;
- Economic, technological, and demographic trends affecting us; and
- The skills of our key personnel and Management.

We may not attempt to supplement this Offering Statement from time to time with new information with respect to our progress and we may not update or revise forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Offering Statement might not occur.

You should rely only on the information contained in this Offering Statement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, do not rely on it.

We are not making an offer in any jurisdiction where such is not permitted. You should assume that the information appearing in this Offering Statement is accurate as of the date on the front cover. Our business or financial condition, the results from our operations and prospects may have materially changed subsequent to that date.

### Do not rely upon any of our forward-looking statements

Although we believe that any forward-looking statements set forth herein are reasonably achievable, any such statements are not to be construed as presenting the actual financial returns which will be experienced by you or a guarantee or promise of any kind that the returns will be as depicted. Rather, they merely represent our judgment, as of the date of this Offering Statement, and based on the assumptions underlying these forward-looking statements, regarding the potential future economic conditions of the Company. There will be differences between the anticipated and actual results because events and circumstances frequently do not occur as expected, and those differences may be material. Additionally, since we are a unique and novel enterprise with no operating history, it is very unlikely that our operating results for any given time period can be accurately predicted even if the overall objectives for the Company are achieved. Consequently, it is possible that you may never realize any return from your investment.

#### **RISKS RELATED TO THE PHARMACEUTICAL INDUSTRY**

#### If we are unable to manage our growth, our business will suffer.

If we fail to manage growth effectively or to develop a successful marketing approach, our business and financial results will be materially harmed. We may also seek to expand our business through complementary or strategic acquisitions of other businesses, products or assets, or through joint ventures, strategic agreements or other arrangements. Any such acquisitions, joint ventures or other business combinations may involve significant integration challenges, operational complexities and time consumption and require substantial resources and effort. It may also disrupt our ongoing businesses, which may adversely affect our relationships with customers, employees, regulators and others with whom we have business or other dealings. Further, if we are unable to realize synergies or other benefits expected to result from any acquisitions, joint ventures or other business combinations, or to generate additional revenue to offset any unanticipated inability to realize these expected synergies or benefits, our growth and ability to compete may be impaired, which would require us to focus additional resources on the integration of operations rather than other profitable areas of our business, and may otherwise cause a material adverse effect on our business, results of operations and financial condition.

#### Our near-term success is dependent upon our ability to commence sales of our drugs.

Our success will depend, in part, upon our ability to continue sales of our drugs. Attracting new customers and distribution networks requires substantial time and expense. Any failure to meet the sales objectives of our drugs would adversely affect our operating results. Many factors could affect the market acceptance and commercial success of our products, including:

- Our ability to convince our potential customers of the advantages and economic value of our drugs over competing products;
- The breadth of our product menu relative to competitors;
- Changes to policies, procedures or currently accepted best practices in clinical development;
- The extent and success of our marketing and sales efforts; and
- Our ability to manufacture in quantity our products and meet demand in a timely fashion.

If we are unable to successfully develop or commercialize new products, our operating results will suffer.

Developing and commercializing a new product is time consuming, costly and subject to numerous factors that may delay or prevent such development and commercialization. Our future results of operations will depend to a significant extent upon our ability to successfully commercialize new products in a timely manner. We face several challenges when developing and commercializing new products, including:

- Our ability to develop products in a timely and cost-efficient manner and in compliance with regulatory requirements, including delays associated with the FDA listing and approval process and our ability to obtain required regulatory approvals in a timely manner, or at all, and maintain such approvals if obtained;
- The success of our clinical testing process to ensure that new products are safe and effective or bioequivalent to the reference listed drug;
- The risk that any of our products presently under development, if and when fully developed and tested, will not perform as expected;
- The risk that legal action may be brought against our generic drug products by our branded drug product competitors, including patent infringement claims among others;
- The availability, on commercially reasonable terms, of raw materials, including Active Pharmaceutical Ingredients ("APIs") and other key ingredients necessary to the development of our generic drug products; and
- Our ability to scale-up manufacturing methods to successfully manufacture commercial quantities of generic drug product in compliance with regulatory requirements.

As a result of these and other difficulties, our products currently in development may or may not receive necessary regulatory approvals on a timely basis or at all, which may result in unsuccessful development or commercialization of new products. If any of our products, when acquired or developed and approved, cannot be successfully or timely commercialized, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing or marketing products will be recouped, even if we are successful in commercializing those products.

#### Our future success depends on our ability to attract and retain talented employees and consultants.

Our future success depends, to a substantial degree, upon the continued service of the members of our management team. The loss of the services of members of our management team, or their inability to perform services on our behalf, could have a material adverse effect on our business, condition (financial and otherwise), prospects and results of operations. Our success also depends, to a large extent, upon the contributions of our sales, marketing, scientific and quality assurance staff. We compete with brand and generic pharmaceutical manufacturers for qualified personnel, and our competitors may offer more favorable employment opportunities than we do. If we are not able to attract and retain the necessary personnel to accomplish our business objectives we could experience constraints that would adversely affect our ability to sell and market our products effectively, to meet the demands of our strategic partners in a timely fashion, and to support our research and development programs. In particular, our sales and marketing efforts depend on the ability to attract and retain skilled and experienced sales, marketing and quality

assurance representatives. Although we believe that we have been successful in attracting and retaining skilled personnel in all areas of our business, we cannot provide assurance that we can continue to attract, train and retain such personnel.

# We will need to increase the size of our organization, and we may encounter difficulties managing our growth, which could adversely affect our results of operations.

We are currently a development stage company. We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our research, development and commercialization effort. To manage any growth, we will be required to continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully manage the expansion of our operations or operate on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

Our ability to develop or license, or otherwise acquire, and introduce new products on a timely basis in relation to our competitors' product introductions involves inherent risks and uncertainties.

Product development is inherently risky, especially for new drugs for which safety and efficacy have not been established and the market is not yet proven. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to terms such as license scope or termination rights. The development and commercialization process, particularly with regard to new drugs, also requires substantial time, effort and financial resources. The process of obtaining FDA approval to manufacture and market new pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. We, or a partner, may not be successful in obtaining FDA approval or in commercializing any of the products that we are developing or licensing.

# The time necessary to develop generic and branded drugs may adversely affect whether, and the extent to which, we receive a return on our capital.

We generally begin our development activities for a new generic drug product several years in advance of the patent expiration date of the brand-name drug equivalent. The development process, including drug formulation, testing, and FDA review and approval, often takes three or more years. This process requires that we expend considerable capital to pursue activities that do not yield an immediate or near-term return. Also, because of the significant time necessary to develop a product, the actual market for a product at the time it is available for sale may be significantly less than the originally projected market for the product. If this were to occur, our potential return on our investment in developing the product, if approved for marketing by the FDA, would be adversely affected and we may never receive a return on our investment in the product. It is also possible for the manufacturer of the brand-name product for which we are developing a generic drug to obtain approvals from the FDA to switch the brand-name drug from the prescription market to the OTC market. If this were to occur, we would be prohibited from marketing our product other than as an OTC drug, in which case revenues could be substantially less than we anticipated.

Developing and commercializing branded pharmaceutical products is generally more costly than developing and commercializing generic products. In order to grow and achieve success in our branded product business, we must continually identify, develop, acquire and license new products that we can ultimately market. There are many difficulties and uncertainties inherent in pharmaceutical research and development, and there is a high rate of failure inherent in new drug discovery and development. Failure can occur at any point in the process, including late in the process after substantial investment. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals and payer reimbursement, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or intellectual property rights of others. Products that do reach the market may ultimately be subject to recalls or other suspensions in sales. Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. Because there is a high rate of failure inherent in the research and development process of new products, there is a significant risk that funds invested in research and development will not generate financial returns. We cannot be certain when or whether any of our products currently under development will be approved or launched or whether, once launched, such products will be commercially successful. We may be required to spend several years and incur substantial expense in completing certain clinical trials. The length of time, number of trial sites and patients required for clinical trials vary substantially, and we may have difficulty finding a sufficient number of sites and subjects to participate in our trials. Delays in planned clinical trials can result in

increased development costs, delays in regulatory approvals and delays in product candidates reaching the market. We rely on independent third-party clinical investigators to recruit subjects and conduct clinical trials in accordance with applicable study protocols and laws and regulations. If regulatory authorities determine that we have not complied with regulations in the development of a product candidate, they may refuse to accept trial data from the site and/or not approve the product candidate, and we would not be able to market and sell that product. If we are not able to market and sell our products after significant expenditures to develop and test them, our business and results of operations could be materially and adversely affected.

# Manufacturing or quality control problems may damage our reputation for quality production, demand costly remedial activities and negatively impact our business, results of operations and financial condition.

As a pharmaceutical company, we are subject to substantial regulation by various governmental authorities. For instance, we must comply with requirements of the FDA and other healthcare regulators with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. We must register our facilities, whether located in the United States or elsewhere, with the FDA as well as regulators outside the United States, and our products must be made in a manner consistent with current good manufacturing practices ("cGMP"), or similar standards in each territory in which we manufacture. The failure of one of our facilities, or a facility of one of our third-party suppliers, to comply with applicable laws and regulations may lead to breach of representations made to our customers or to regulatory or government action against us related to products made in that facility.

In addition, the FDA and other agencies periodically inspect our manufacturing facilities. Following an inspection, an agency may issue a notice listing conditions that are believed to violate cGMP or other regulations, or a warning letter for violations of "regulatory significance" that may result in enforcement action if not promptly and adequately corrected. We remain committed to continuing to improve our quality control and manufacturing practices; however, we cannot be assured that the FDA will continue to be satisfied with our corrective actions and with our quality control and manufacturing systems and standards. Failure to comply strictly with these regulations and requirements may damage our reputation and lead to financial penalties, compliance expenditures, the recall or seizure of products, total or partial suspension of production and/or distribution, withdrawal or suspension of the applicable regulator's review of our submissions, enforcement actions, injunctions and criminal prosecution. Further, other federal agencies, our customers and partners in our alliance, development, collaboration and other partnership agreements with respect to our products and services may take any such FDA observations or warning letters into account when considering the award of contracts or the continuation or extension of such partnership agreements. Because regulatory approval to manufacture a drug is site-specific, the delay and cost of remedial actions, or obtaining approval to manufacture at a different facility, could negatively impact our business. Any failure by us to comply with applicable laws and regulations and/or any actions by the FDA and other agencies as described above could have a material adverse effect on our business, financial position and results of operations.

# We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business.

In the United States, many of our products are eligible for reimbursement under federal and state health care programs such as Medicaid, Medicare, TriCare, and/or state pharmaceutical assistance programs, and as a result, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are, and will be, applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to: (i) the U.S. Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, as a means of inducing, or in exchange for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent; (iii) the U.S. Health Insurance Portability and Accountability Act of 1996, ("HIPAA"), which among other things created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and our implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information and place restrictions

on the use of such information for marketing communications; (iv) the U.S. Physician Payments Sunshine Act, which among other things, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under a federal healthcare program to report annually information related to "payments or other transfers of value" made to physicians and teaching hospitals, and ownership and investment interests held by certain healthcare professionals and their immediate family members, and similar state laws; (v) the government pricing rules applicable to the Medicaid, Medicare Part B, 340B Drug Pricing Program, the U.S. Department of Veterans Affairs program, the TRICARE program, and state price reporting laws; and (vi) state and foreign law equivalents of each of the above U.S. laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts. Violations of the fraud and abuse laws may result in severe penalties against us and/or our responsible employees, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Defense of litigation claims and government investigations can be costly, timeconsuming, and distract management, and it is possible that we could incur judgments or enter into settlements that would require us to change the way we operate our business. We are committed to conducting the sales and marketing of our products in compliance with the healthcare fraud and abuse laws, but certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that govern our activities, such as federal and state anti-kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn. While we manage our business activities to comply with these statutory provisions, due to their breadth, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the DOJ and other agencies have increased their enforcement activities with respect to the sales, marketing, research and similar activities of pharmaceutical companies in recent years, and many pharmaceutical companies have been subject to government investigations related to these practices. A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacturing and/or distribution activities, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product approvals, exclusion from participation in government healthcare programs and other sanctions.

Any of these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows.

# Approvals for our new generic drug products may be delayed or become more difficult to obtain if the FDA institutes changes to its approval requirements.

The FDA may institute changes to its ANDA approval requirements, such as implementing new or additional fees similar to the fees imposed by the Generic Drug Fee User Amendments of 2012 ("GDUFA") and its second iteration (GDUFA II), which may make it more difficult or expensive for us to obtain approval for our new generic products. The FDA may also implement other changes that may directly affect some of our ANDA filings pending approval from the FDA, such as changes to guidance from the FDA regarding bioequivalency requirements for particular drugs. Such changes may cause our development of such generic drugs to be significantly more difficult or result in delays in FDA approval or result in our decision to abandon or terminate certain projects. Any changes in FDA requirements may make it more difficult for us to file ANDAs or obtain approval of our ANDAs and generate revenues and thus have a material adverse effect on our business, results of operations and financial condition.

# The testing required for the regulatory approval of our products is conducted primarily by independent third parties.

Any failure by any of these third parties to perform this testing properly and in a timely manner may have an adverse effect upon our ability to obtain regulatory approvals. Our applications for regulatory approval of our products, including both internallydeveloped and in-licensed products, incorporate the results of testing and other information that is conducted or gathered primarily

by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, contract research organizations or independent research facilities). Our ability to obtain and maintain regulatory approval of the products being tested is dependent upon the quality of the work performed by these third parties, the quality of the third parties' facilities, and the accuracy of the information provided by third parties. We have little or no control over any of these factors. If this testing is not performed properly, our ability to obtain or maintain regulatory approvals, and to launch or continue selling products, could be restricted or delayed.

# Our approved products may not achieve expected levels of market acceptance. Even if we are able to obtain regulatory approvals for our new products, the success of those products is dependent upon market acceptance.

Levels of market acceptance for our new products could be affected by several factors, including:

- The availability of alternative products from our competitors;
- The prices of our products relative to those of our competitors;
- The timing of our market entry;
- The ability to market our products effectively at the retail level;
- The perception of patients and the healthcare community, including third-party payers, regarding the safety, efficacy and benefits of our drug products compared to those of competing products; and
- The acceptance of our products by government and private formularies.

Some of these factors will not be in our control, and our products may not achieve expected levels of market acceptance. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which can call into question the utilization, safety and efficacy of products.

# Federal regulation of arrangements between manufacturers of branded and generic products could adversely affect our business.

As part of the Medicare Prescription Drug and Modernization Act of 2003, companies are required to file with the FTC and the DOJ certain types of agreements entered into between branded and generic pharmaceutical companies related to the manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which brand drug manufacturers resolve intellectual property litigation and other disputes with generic pharmaceutical companies and could result generally in an increase or lengthening of litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities. The impact of this requirement, the pending legislation and the potential private-party lawsuits associated with arrangements between brand and generic drug manufacturers is uncertain and could adversely affect our business.

# We may be involved in various legal proceedings which may force us to incur substantial expense to defend and/or expose us to substantial liability.

We may become a party to litigation in the ordinary course of our business, including, among others, matters alleging product liability, other intellectual property rights infringement, violations of securities laws, employment discrimination or breach of commercial contract. In general, litigation claims can be expensive and time consuming to bring or defend against and could result in settlements or damages that could have a material adverse effect on our business, results of operations and financial condition.

# If we fail to obtain exclusive marketing rights for our products or fail to introduce our products on a timely basis, our revenues, gross margin and operating results may decline significantly.

The Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act (the "FDCA") provide for a period of 180 days of generic marketing exclusivity for any applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding branded drug (commonly referred to as a "Paragraph IV certification"). "First filers" are often able to price the applicable generic drug to yield relatively high gross margins during this 180-day marketing exclusivity period.

With respect to our generic products, ANDAs containing Paragraph IV certifications generally become the subject of patent litigation that can be both lengthy and costly. There is no certainty that we will prevail in any such litigation, that we will be the first to file and thus granted the 180-day marketing exclusivity period, or, if we are granted the 180- day marketing exclusivity period, that we will not forfeit such period. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other first filers.

In addition, branded drug product companies often authorize a generic version of the corresponding branded drug product to be sold during any period of marketing exclusivity that is awarded (described further below), which reduces gross margins during the marketing exclusivity period. Branded drug product companies may also reduce the price of their branded drug product to compete directly with generic drug products entering the market, which would similarly have the effect of reducing gross margins. Furthermore, timely commencement of the litigation by the patent owner imposes an automatic stay of ANDA approval by the FDA for 30 months, unless the case is decided in the ANDA applicant's favor during that period. Finally, if the court decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires, and the applicant forfeits the 180-day marketing exclusivity.

Our future profitability depends, to a significant extent, upon our ability to introduce, on a timely basis, new generic drug products that are either the first-to-market (or among the first-to-market) or that otherwise can gain significant market share. The timeliness of our product introductions is dependent upon, among other things, the timing of regulatory approval of our products, which to a large extent is outside of our control, as well as the timing of the introduction of competing products. As additional distributors introduce comparable generic pharmaceutical products, price competition intensifies, market access narrows, and product sales prices and gross margins decline, often significantly and rapidly. Accordingly, our revenues and future profitability are dependent, in large part, upon our ability or the ability of our development partners to file ANDAs with the FDA in a timely and effective manner or, alternatively, to enter into contractual relationships with other parties that have obtained marketing exclusivity. No assurances can be given that we will be able to develop and introduce successful products in the future within the time constraints necessary to be successful. If we or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or to partner with other parties that have obtained marketing exclusivity, our revenues, gross margin and operating results may decline significantly and our prospects and business may be materially adversely affected.

With respect to our branded products, generic equivalents for branded pharmaceutical products are typically sold at lower prices than the branded products. The regulatory approval process in the United States and European Union exempts generic products from costly and time-consuming clinical trials to demonstrate their safety and efficacy and rely instead on the safety and efficacy of prior products. After the introduction of a competing generic product, a significant percentage of the prescriptions previously written for the branded product are often written for the generic version. In addition, legislation enacted in most U.S. states allows or, in some instances mandates, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Pursuant to the provisions of the Hatch-Waxman Act, manufacturers of branded products' patents, but it is possible for generic manufacturers to offer generic products while such litigation is pending. As a result, branded products typically experience a significant loss in revenues following the introduction of a competing patent. Our branded pharmaceutical products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of the branded pharmaceutical products we sell, because our patent protection expires or because our patent protection is not sufficiently broad or enforceable.

# Our business is highly dependent on market perceptions of us and the safety and quality of our products. Our business, products or product pricing could be subject to negative publicity, which could have a material adverse effect on our business, results of operations and financial condition.

Market perceptions of our business are very important to us, especially market perceptions of the safety and quality of our products. If any of our products or similar products that other companies distribute are subject to market withdrawal or recall or are

proven to be, or are claimed to be, harmful to consumers, then this could have a material adverse effect on our business, results of operations and financial condition. Also, because our business is dependent on market perceptions, negative publicity associated with product quality, illness or other adverse effects resulting from, or perceived to be resulting from, our products could have a material adverse impact on our business, results of operations and financial condition. The generic pharmaceutical industry has also in recent years been the subject of significant publicity regarding the pricing of pharmaceutical products more generally, including publicity and pressure resulting from prices charged by competitors and peer companies for new products as well as price increases by competitors and peer companies on older products that the public has deemed excessive.

Any downward pricing pressure on the price of certain of our products arising from social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition. Accompanying the press and media coverage of pharmaceutical pricing practices and public complaints about the same, there has been increasing U.S. federal and state legislative and enforcement interest with respect to drug pricing. For instance, the United States Department of Justice issued subpoenas to pharmaceutical companies seeking information about the sales, marketing and pricing of certain generic drugs. In addition to the effects of any investigations or claims brought against us, our business, results of operations and financial condition could also be adversely affected if any such inquiries, of us or of other pharmaceutical companies or the industry more generally, were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products.

# We face intense competition in the pharmaceutical industry from both brand and generic drug product companies, which could significantly limit our growth and materially adversely affect our financial results.

The pharmaceutical industry is highly competitive. The principal competitive factors in the pharmaceutical market include:

- Introduction of other generic drug manufacturers' products in direct competition with our generic drug products;
- Introduction of authorized generic drug products in direct competition with our products, particularly during exclusivity periods;
- The ability of generic drug product competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits;
- Consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups;
- The willingness of generic drug customers, including wholesale and retail customers, to switch among products of different pharmaceutical manufacturers;
- Pricing pressures by competitors and customers;
- A company's reputation as a manufacturer and distributor of quality products;
- A company's level of service (including maintaining sufficient inventory levels for timely deliveries);
- Product appearance and labeling; and
- A company's breadth of product offerings.

Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than us. Consequently, some of our competitors may be able to develop products and/or processes competitive with, or superior to, our products. Furthermore, we may not be able to (i) differentiate our products from those of our competitors, (ii) successfully develop or introduce new products on a timely basis or at all that are less costly than those of our competitors, or (iii) offer customers payment and other commercial terms as favorable as those offered by our competitors. The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant change. We expect competition to intensify as technological advances and consolidation continues. New developments by other manufacturers and distributors could render our products uncompetitive or obsolete.

We also face price competition generally as other generic manufacturers enter the market. Any such price competition may be especially pronounced where our competitors source their products from jurisdictions where production costs may be lower (sometimes significantly) than our production costs, especially lower-cost foreign jurisdictions. Any of these factors could result in reductions in our sales prices and gross margin. This price competition has led to an increase in demands for downward price adjustments by generic pharmaceutical distributors. Our principal strategy in addressing our competition is to offer customers a consistent supply of our generic drug products, as well as to pursue product opportunities with the potential for limited competition, such as high-barrier-to-entry first-to-file or first-to-market products. There can be no assurance, however, that this strategy will enable us to compete successfully in the generic drug product industry or that we will be able to develop and implement any new or additional viable strategies.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. Authorized generic drug products are generic drug products that are introduced by brand companies, either directly or through third parties, under the brand's New Drug Application ("NDA") approval for our own branded drug. Authorized generics do not face any regulatory barriers to introduction and are not prohibited from sale during the 180-day marketing exclusivity period granted to the FTF ANDA applicant. The sale of authorized generics adversely impacts the market share of a generic drug product that has been granted 180 days of marketing exclusivity. This is a significant source of competition for us, because an authorized generic drug product. Such actions have the effect of reducing the potential market share and profitability of our generic drug products and may inhibit us from developing and introducing generic pharmaceutical drug products corresponding to certain branded drugs.

# As our competitors introduce their own generic equivalents of our generic drug products, our revenues and gross margin from such products generally decline, often rapidly.

Revenues and gross margin derived from generic pharmaceutical products often follow a pattern based on regulatory and competitive factors that we believe are unique to the generic pharmaceutical industry. As the patent(s) for a brand name product or the statutory marketing exclusivity period (if any) expires, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product is often able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for their own generic versions, that market share, and the price of that product, will typically decline depending on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. We cannot provide assurance that we will be able to continue to develop such products or that the number of our competitors for any given product will not increase to such an extent that we may stop marketing a generic drug product for which we previously obtained approval, which may have a material adverse impact on our revenues and gross margin.

# We expend a significant amount of resources on research and development, including milestones on in-licensed products, which may not lead to successful product introductions.

Much of our development effort is focused on technically difficult-to-formulate products and/or products that require advanced manufacturing technology. We expend significant resources on research and development primarily to enable us to manufacture and market FDA approved pharmaceuticals in accordance with FDA regulations. We have entered into, and may in the future enter into, agreements that require us to make significant milestone payments upon achievement of various research and development events and regulatory approvals. As we continue to develop and in-license new products, we will likely incur increased research and licensing expenses. Because of the inherent risk associated with research and development efforts in the industry, particularly with respect to new drugs, our research and development expenditures may not result in the successful introduction of FDA-approved pharmaceutical products. Additionally, after we or our development partners submit an ANDA, the FDA may request that additional studies be conducted. As a result, we may be unable to reasonably determine the total research and development costs required to develop a particular product. Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not ultimately able to successfully introduce new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected.

# We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

# R E G U L A T I O N C R O W D F U N D I N G O F F E R I N G S T A T E M E N T

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. We have also outsourced significant elements of our information technology infrastructure; as a result, we manage independent vendor relationships with third parties who are responsible for maintaining significant elements of our information technology systems and infrastructure and who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third-party vendors, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors. These systems are also vulnerable to attacks by malicious third parties and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties. Maintaining the secrecy of confidential, proprietary, and/or trade secret information is important to our competitive business position. While we have taken steps to protect such information and have invested in systems and infrastructures to do so, there can be no guarantee that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations and/or cash flow.

# Our business and product candidates are subject to extensive governmental regulation and oversight, and our failure to comply with applicable regulatory requirements could harm our business.

Our product candidates and operations are subject to extensive regulation in the United States by the FDA and by regulatory agencies in other countries where we anticipate conducting business activities. The FDA regulates the development, testing, manufacturing, labeling, storage, record-keeping, promotion, marketing, sales, distribution and post-market support and reporting of medical devices in the United States. The regulations to which we are subject are complex and may become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

We are currently, and in the future our contract manufacturers may be, subject to various governmental regulations related to the manufacturing of our product candidates, and we may incur significant expenses to comply with, experience delays in our product commercialization as a result of and be subject to material sanctions if we or our contract manufacturers violate these regulations.

Our manufacturing processes and facility are required to comply with the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of our drugs. Although we believe we are compliant with the QSRs, the FDA enforces the QSR through periodic announced or unannounced inspections of manufacturing facilities. We have been, and anticipate in the future being, subject to such inspections, as well as to inspections by other federal and state regulatory agencies. We are required to register our manufacturing facility with the FDA and list all devices that are manufactured. The suppliers of our components are also required to comply with the QSR and are subject to inspections. We have limited ability to ensure that any such third-party manufacturers will take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with our products or manufacturing processes, including our failure or the failure of one of our third-party manufacturers to take satisfactory corrective action in response to an adverse QSR inspection, can result in, among other things:

- Administrative or judicially imposed sanctions;
- Injunctions or the imposition of civil penalties;
- Recall or seizure of our drugs;

- Total or partial suspension of production or distribution;
- The FDA's refusal to grant future clearance or pre-market approval for our product candidates;
- Withdrawal or suspension of marketing clearances or approvals;
- Clinical holds;
- Warning letters;
- Refusal to permit the import or export of our product candidates; and
- Criminal prosecution of us or our employees.

Any of these actions, in combination or alone, could prevent us from marketing, distributing, or selling our products and would likely harm our business. In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could expose us to product liability or other claims, including contractual claims from parties to whom we sold products and harm our reputation with customers. A recall involving any of our product candidates would be particularly harmful to our business and financial results and, even if we remedied a particular problem, would have a lasting negative effect on our reputation and demand for our products.

#### Our collaborations with outside scientists and consultants may be subject to restriction and change.

We work with scientists at academic and other institutions, and consultants who assist us in our research, development, and regulatory efforts, including the members of our medical advisory board. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice on our programs. These scientists and consultants are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product or compound that is more scientifically interesting to their or her professional interests, their or her availability to remain involved in our clinical trials could be restricted or eliminated. We have entered into or intend to enter into non-competing directly with us or working for our competitors for a limited period. However, under current law, we may be unable to enforce these agreements against certain of our employees and it may be difficult for us to restrict our competitors from gaining the expertise our former employees gained while working for us. If we cannot enforce our employees' non-compete agreements, we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

# **RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

## If we are unable to adequately protect our proprietary technology or maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which could harm our business, financial condition and results of operations.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. We have filed and are actively pursuing patent applications for our product candidates and manufacturing processes. Our patents may not have, or our pending patent applications that mature into issued patents may not include, claims with a scope sufficient to protect our products, any additional features we develop for our current products or any new products. Other parties may have developed technologies that may be related or competitive to our products, may have filed or may file patent applications and may have received or may

receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third-party receiving the patent right sought by us, which in turn could affect our ability to commercialize our implant systems. Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees.

The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If any of these developments were to occur, they each could have a negative impact on our business and competitive position.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, our financial position and results of operations could be negatively impacted. In addition, if a court found that valid, enforceable patents held by third parties covered one or more of our products, our financial position and results of operations could be harmed.

Competitors may also be able to design around our patents and licenses. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries. If these developments were to occur, they could have a material adverse effect on our sales.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we will seek to protect, in part, by entering into confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

# From time to time we may need to rely on licenses to proprietary technologies, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially market our products may be inhibited or prevented, which could have a material adverse effect on our business, results of operations and financial condition.

#### We depend on our ability to protect our intellectual property and proprietary rights.

Our success depends on our ability to protect and defend the intellectual property rights associated with our current and future products. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that may be confused with, our products, and our generic competitors may obtain regulatory approval to make and distribute generic versions of our branded products. Some patent applications in the United States are maintained in secrecy or are not published until the resulting patents issue. We also cannot be certain that patents will be issued with respect to any of our patent applications or that any existing or future patents issued to or licensed by us will provide competitive advantages for our products or will not be challenged, invalidated, circumvented or held unenforceable in proceedings commenced by our competitors or other third parties. Furthermore, our patent rights may not prevent or limit our present and future competitors from developing, making, importing, using or commercializing products that are functionally similar to our products. We rely particularly on trade secrets, trademarks, unpatented proprietary expertise and continuing innovation that we seek to protect, in part, by registering and using marks; and by entering into confidentiality agreements with licensees, suppliers, employees, consultants and other parties we use this approach to protecting our intellectual property in large part because few of our products are protected by patents. We cannot provide assurance that these agreements will not be breached or circumvented. We also cannot be certain that we will have recourse to adequate remedies in the event of a breach of such agreements. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. We cannot be sure that our trade secrets and proprietary technology will not be independently developed or otherwise become known by our competitors or, if patents are not issued with respect to our internally-developed products, that we will be able to maintain the confidentiality of information relating to these products. In addition, efforts to ensure our intellectual property rights may be costly, time-consuming and/or ultimately unsuccessful. We cannot be sure that we will have the resources to protect our own rights against infringement by third parties.

# We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our products, if approved.

We have licensed certain rights in a patent to a patent. Our license imposes various obligations on us, and provides the licensor the right to terminate the license in the event of our material breach of the license agreement, our failure to initiate or complete development of a licensed product, or our commencement of an action seeking to have a licensed patent right declared invalid. Termination of our license would result in our loss of the right to use the licensed intellectual property, which would materially adversely affect our ability to develop and commercialize our products, as well as harm our competitive business position and our business prospects.

We may enter into additional licenses to third-party intellectual property that are necessary or useful to our business. Future licensors may also allege that we have breached our license agreement and may accordingly seek to terminate our license with them. In addition, future licensors may have the right to terminate our license at will. Any termination could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize our product line, if approved, as well as harm our competitive business position and our business prospects.

#### **RISKS ASSOCIATED WITH THE COMPANY AND THIS OFFERING**

#### Our operating results are affected by many factors and may fluctuate significantly on a quarterly basis.

Our operating results may vary substantially from quarter to quarter and may be greater or less than those achieved in the immediately preceding period or in the comparable period of the prior year. Factors that may cause quarterly results to vary include, but are not limited to, the following:

- The number of new product introductions by us;
- Losses related to inventory write-offs;
- Marketing exclusivity, if any, which may be obtained on certain new products;
- The level of competition in the marketplace for certain products;
- Our ability to create demand in the marketplace for our products;

- Availability of raw materials and finished products from suppliers;
- Our ability to manufacture products at our manufacturing facilities;
- The scope and outcome of governmental regulatory actions;
- Our dependence on a small number of products for a significant portion of net revenue or income;
- Legal actions against our generic products brought by brand competitors, and legal challenges to our intellectual property rights by generic competitors;
- Price erosion and customer consolidation; and
- Significant payments (such as milestones) payable by us under collaboration, licensing, and development agreements to
  our partners before the related product has received FDA approval.

The profitability of our product sales is also dependent upon the prices we are able to charge for our products, the costs to purchase products from third parties, and our ability to manufacture our products in a cost effective manner. If our revenues decline or do not grow as anticipated, we may not be able to reduce our operating expenses to offset such declines. Failure to achieve anticipated levels of revenues could, therefore, significantly harm our operating results for a particular fiscal period.

#### We may lack sufficient capitalization

We are not required to maintain any minimum level of permanent working capital reserves. Our available working capital will be allocated toward due diligence in connection with the development of new drug products and development of select prospects, and/or administrative and operational costs associated with such intended activities (see "Use of Proceeds"). To the extent that expenses increase or unanticipated expenses arise and accumulated reserves are insufficient to meet such expenses, we would be required to obtain additional funds, if available.

Due to our limited capitalization prior to this Offering (see our financial statements in the Exhibit section of this Offering Statement) and the fact that the resources of our current Shareholders are limited, there would be limited resources to pursue in the event that we were unable to honor our financial commitments. The ability of the Company to continue to grow will depend upon our ability to raise additional capital. There can be no assurance that any revenues or capital can be generated or found at a time or on such terms and conditions as will permit the Company to achieve its intended objectives. Financial market conditions in the future may affect the availability and cost of capital or other forms of financing, making working capital difficult or costly to obtain. In the event the Company is unable to raise capital or generate revenues or monetize assets within a reasonable period of time, the Company will be required to obtain the necessary funds through alternative sources, if available. If additional funds are not available from any source, the Company could be subject to bankruptcy in the event it is unable to satisfy its creditors and/or the risk of losing its assets through foreclosure to the extent they were pledged as collateral or security.

#### We run the risk of incurring uninsured losses

Depending upon our available capital, we intend to arrange for comprehensive insurance on the Company's acquired assets to the extent possible. However, there are certain types of losses (generally of a catastrophic nature, such as earthquakes, floods, terrorist attacks and wars) which are either uninsurable or not economically insurable. Should such a disaster occur to or cause damage to or the destruction of our assets, we could lose our invested capital and anticipated income or sales revenue from the same. Such a loss would require the Company to obtain additional funds to meet its obligations.

#### We may pivot

There is a distinct possibility that we may pivot away from our original objectives and strategies as outlined in this Offering Statement and embark on one or more ventures or business models that we have not yet presently contemplated.

### This Offering is not registered under federal or state securities laws

This Offering has not been registered under the Securities Act of 1933, as amended, nor registered under the securities laws of any state or jurisdiction. We do not intend to register this Offering at any time in the future. Thus, you will not enjoy any benefits that may have been derived from registration and corresponding review by regulatory officials. You must make your own decision as to investing in the Company with the knowledge that regulatory officials have not commented on the adequacy of the disclosures contained in this Offering Statement or on the fairness of the terms of this Offering.

#### We could incur securities regulatory action

Prior to the date on the cover of this Offering Statement the Company may have conducted one or more private placement offerings of equity in the Company. We believe the placement of such securities were conducted in compliance with existing federal and state securities laws and exemptions from registration. However, any one or more of such placements of such securities could be found by the SEC and/or one or more state securities regulatory agencies to have not been conducted in accordance with the requirements of available exemptions and/or constitute a single offering of securities, which finding could lead to a disallowance of exemptions from registration. Such could give rise to various legal actions against the Enterprise(s), the Company, and/or its Affiliates brought by federal or state regulatory agencies and/or private litigants. In such event there can be no assurance that such proceedings would be settled in our favor or that such may not adversely affect us.

#### We lack a relevant operating history

The Company lacks a relevant operating history in the pharmaceutical industry. As a result, we are subject to all the risks and uncertainties which are characteristic of a new business enterprise, including the substantial problems, expenses and other difficulties typically encountered in the course of establishing a business, organizing operations and procedures, etc. The likelihood of our success must be considered in light of these potential problems, expenses, complications, and delays.

### We cannot forecast or predict the outcome of our activities

We are dependent upon proceeds of this Offering to fund our operations and pursue our objectives. There is no information at this time upon which to base an assumption that our plans will materialize or prove successful. There can be no assurance that our planned endeavors will result in any operational revenues or profits in the future – especially if our acquired assets prove to be commercially unprofitable. This, coupled with our limited operating history, makes prediction of our future operating results difficult, if not impossible. Because of these reasons, you should be aware that your entire investment in the Company's Shares is at risk.

#### We are substantially dependent upon third parties

We will be substantially dependent upon third-party advisors and consultants retained by the Company including, but not limited to, engineers, investment bankers, surveyors, appraisers, analysts, investment advisors, accountants, money managers, attorneys, risk managers, statisticians, computer technicians, realtors, mortgage bankers, consultants, geologists, geophysicists, landmen, etc., some of whom may be Affiliates of the Company. We may also enlist the Services of other professionals if deemed in the best interest of the Company. The death or continuing disability of any of these persons may have a materially adverse effect upon our ability to conduct business.

#### Transferability of Shares and/or CZ48 Drug Revenue Interests you purchase will be restricted

The Shares and/or CZ48 Drug Revenue Interests offered by way of this Offering Statement have not been registered with the Commission or any government's securities authority and will be restricted and therefore cannot be resold unless they are also registered or unless an exemption from registration is available. Therefore, you should be prepared to hold the Shares for at least one (1) year and perhaps even an indefinite period of time.

# There is no liquidity associated with the Shares or CZ48 Drug Revenue Interests

Neither the Shares nor CZ48 Drug Revenue Interests will not be listed on any national securities exchange or included for quotation through an inter-dealer quotation system of a registered national securities association. The Shares and CZ48 Drug Revenue Interests constitute a new issue of securities with no established trading market. Furthermore, there can be no assurance that there will be any regular secondary market following the completion of the Offering. Therefore, an investment in these securities should be considered non-liquid. In addition, no assurance can be given that the initial Offering price for these securities will continue for any period of time.

#### We arbitrarily determined the Offering price of Shares and terms of CZ48 Drug Revenue Interests

The price per Share and the terms of the CZ48 Drug Revenue Interests bears no relationship to our assets, opportunities, net worth, or any recognized criteria of value and should not be considered to be an indication of the actual value of the Shares.

#### All financial forecasts are subject to limitations

If any financial forecasts are utilized by the Company in connection with this Offering, they have been prepared solely by the Company's management. Such forecasts, if any, have not been compiled or reviewed by independent accountants, and, accordingly, no opinion or other form of assurance is expressed. Because such projections are based on a number of assumptions and are subject to significant uncertainties and contingencies, many of which are beyond the control of the Company, there can be no assurance that such projections, if any, will be realized as actual results may vary significantly and materially from the results included. Such projections, if any, should not be regarded as a representation that the projections will be achieved, nor should the projections be relied upon in purchasing the Shares offered hereby and are qualified in their entirety by the content of this Offering Statement.

#### Our officers, directors or key advisors may have conflicts of interest vis-à-vis the Company

There are conflicts of interest inherent in the activities of the Company. Our officers, directors and/or our key advisors or their Affiliates or personnel act in a similar capacity for other concerns within the pharmaceutical industry or elsewhere. Such persons intend to continue to manage such concerns and plan to do so in the future. Although we do not currently anticipate problems, any additional responsibilities taken on by such persons may cause them to devote less time to the business of the Company than is necessary or prudent. Also, many of our key personnel may receive equity in the Company.

Certain services to be provided to the Company, such as legal, accounting, marketing or consulting services, may be performed by Affiliates or personnel of the Company or related parties under common control. Also, our officers, directors and/or key advisors may collect fees, salaries, and/or related costs in connection with managing Company affairs paid out of the net proceeds of this Offering. Consequently, there is the possibility that if the Company doesn't perform well, our officers, directors, key advisors or other personnel or related parties may still realize a profit even though the Company does not.

Conflicts of interest for the above-referenced persons and others associated with the Company by way of contract may also arise. Such individuals, either directly or indirectly, may provide services to other pharmaceutical companies and may acquire pharmaceutical assets for their own account and the account of others. In addition, such persons and/or their Affiliates are presently engaged in the pharmaceutical business independent of the Company and conduct such activities with other companies or private partners. Such persons may also be involved with pharmaceutical companies and in other aspects of private capital formation. All of these activities may result in conflicts of interest.

#### You should seek out independent legal advice

Neither we nor our attorneys intend to give you any legal advice or counsel whatsoever. We strongly recommend you consult with your legal advisors regarding the inherit risks of the Company before investing.

# We are dependent upon the proceeds of this Offering to commence operations

We are dependent upon the proceeds of this Offering in order to commence due diligence towards acquiring interest in pharmaceutical prospects and to otherwise commence operations as a going concern.

#### **OTHER POSSIBLE RISKS**

#### We may be adversely impacted from the effects of the current and ongoing COVID-19 pandemic

Major health epidemics, such as the current and ongoing outbreak caused by a coronavirus (COVID- 19), and other outbreaks or unforeseen or catastrophic events could disrupt and adversely affect our operations, financial condition, and business. The United States and other countries have experienced, and may experience in the future, major health epidemics related to viruses, other pathogens, and other unforeseen or catastrophic events, including natural disasters, extreme weather events, power loss, government lockdowns, acts of war, and terrorist attacks. For example, there was an outbreak of COVID-19, a novel virus, which has spread to the United States and other countries and declared a global pandemic. The global spread of COVID-19 has created significant volatility and uncertainty in financial markets. There remains significant uncertainty relating to the potential impact of COVID-19 on our business. The extent to which COVID-19 impacts our current capital raise and our ability to obtain future financing, as well as our results of operations and financial condition, generally, will depend on future developments which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions taken by governments and private businesses to contain COVID-19 or treat its impact.

#### We may be subject to other risks

The foregoing represent the Company's best attempt to identify the various risks in connection with your investment in the Company. It does not purport to be complete and may not adequately cover all activities in which we may be engaged nor all the risks we will be subject to, either directly or indirectly, as a result of pursuing our objectives. You are encouraged and entitled to ask questions of and receive answers from the Company's management in order to assess the merits and risks of investing in the Company's Shares.

#### THE OFFERING

#### PURPOSE

The purpose of this Offering is to provide the Company with working capital.

#### ESTIMATED USE OF PROCEEDS

We intend to use the net proceeds received from this Offering for general working capital purposes, including, but not limited to, phase II clinical trials of our CZ48 lead drug, research, cost reduction efforts, hiring new team members, and/or any other business purpose. Inasmuch as it is impossible to predict exact costs and the expenses necessary to conduct the business of the Company, actual expenditures could vary substantially and materially from any estimates or forecasts supplied by our Management.

Inasmuch as it is impossible to predict exact costs and the expenses necessary to conduct the business of the Company, actual expenditures could vary substantially and materially from the following estimated forecasts:

	If Target Offering	If Maximum Amount Sold*
	Amount Sold	
	(1)	
Total Proceeds:	<u>\$10,000</u>	<u>\$5,000,000</u>

Less: Offering Expenses

<sup>\*</sup>May be expanded up to USD \$5,000,000 in the Company's sole discretion in the event the Company obtains audited financial statements in which case this Offering Statement will be updated and/or supplemented.

Costs of Capital: Sales Commissions, Finder Fees, Portal Fees payable to the Company's intermediary Silicon Prairie Holdings Inc., and/or Offering Marketing Allowances payable to others, some or all of whom may be Affiliates of the Company	\$3,000	\$52,500
Net Proceeds:	<u>\$7,000</u>	<u>\$4947,500</u>
Use of Net Proceeds Working Capital	\$7,000	\$4947,500

\$7,000

\$4947,500

# Total Use of Net Proceeds:

#### FOOTNOTES TO TABLE:

(1) The Company's intermediary, Silicon Prairie Holdings Inc., shall receive a fee of \$2,500 plus 5% of funds raised up to \$5,000,000.

### **CLOSING AND DELIVERY OF SECURITIES**

The initial Closing of the Offering shall occur upon the earlier to occur of either (a) five (5) days after subscriptions of at least USD \$10,000 (the "Target Offering" amount) have been received by the Company, or (b) 360 days after the date on the cover of this Offering Statement (the initial "Closing Date" or initial "Deadline"). The Closing Date and/or Deadline may be extended at any time.

At least 48 hours prior to a Closing Date or Deadline, you will receive a notification via email stating either (a) your subscription has been accepted and will thereafter be electronically recorded in the Company's books and records, or (b) your subscription is being refunded.

After the initial Closing Date or initial Deadline, subsequent Closings may occur on a rolling basis in the Company's sole discretion.

#### **CANCELLATION POLICY**

NOTE: You may cancel your investment commitment (subscription) until 48 hours prior to the Deadline identified in these offering materials (see above).

Our intermediary will notify you when the Target Offering amount has been met.

If we reach the Target Offering amount prior to the Deadline identified in the offering materials (see above), we may close the offering early if we provide notice about the new Offering Deadline at least five (5) business days prior to such new Offering Deadline (absent a material change that would require an extension of the Offering and reconfirmation of your investment commitment).

If you do not cancel your investment commitment (subscription) before the 48-hour period prior to the Offering Deadline, the funds will be released to the Company upon Closing of the Offering and you will receive securities in exchange for your investment.

If you do not reconfirm your investment commitment (subscription) after a material change is made to the Offering, your investment commitment (subscription) will be cancelled and your committed funds will be returned.

#### **OWNERSHIP AND CAPITAL STRUCTURE**

#### THE OFFERING

#### **Shares of Common Stock**

The Shares of Common Stock (the "Shares" or "Equity") have standard voting rights and are entitled to share in dividends when or if declared by the board of directors subordinate to any preferred shares and provided the Company's debts and other obligations have been satisfied and/or are current.

#### **Voting Rights**

Shares of Common Stock have voting rights (i.e., one (1) vote per Share). For a more complete description of voting rights, see the Company's Bylaws attached hereto as an Exhibit.

#### **Revenue Interests in CZ48 Drug**

Share Subscribers in this Offering shall also be entitled to the assignment of a revenue interest in any future sales of the CZ48 Drug at the rate set forth in Schedule B of the attached Stock Purchase and CZ48 Drug Revenue Agreement (see the Exhibit section of this Offering Statement). If this Offering is fully subscribed for \$5,000,000, then up to approximately 30 % of the Company's revenue interest in the CZ48 drug will be allocated accordingly directly to subscribers.

#### **Other Securities**

We also reserve the right to issue securities of any kind at any time on terms other than the terms set forth in this Offering Statement.

#### MODIFICATIONS OF OFFERING TERMS

The terms of the securities being offered may be modified through one or more Side Letters. A "Side Letter" is any informal written agreement or letter of understanding entered into by the Company with one or more Persons which may materially obligate the Company and/or modify the terms of this Offering, a Stock Purchase Agreement, and/or other preferences or terms which may be materially different than the terms contemplated by this Offering Statement.

# **RESTRICTIONS ON TRANSFER OF THE SECURITIES BEING OFFERED**

The Securities being offered may not be transferred by any purchaser of such Securities during the one year period beginning when the Securities were issued, unless such Securities are transferred:

- (1) to the Issuer (the Company);
- (2) to an accredited investor;
- (3) as part of an offering registered with the U.S. Securities and Exchange Commission; or

(4) to a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance.

# NOTE: The term "accredited investor" means any person who comes within any of the categories set forth in Rule 501(a) of Regulation D, or who the seller reasonably believes comes within any of such categories, at the time of the sale of the securities to that person.

The term "member of the family of the purchaser or the equivalent" includes a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the purchaser, and includes adoptive relationships. The term "spousal equivalent"

#### means a cohabitant occupying a relationship generally equivalent to that of a spouse.

#### **DESCRIPTION OF THE ISSUER'S SECURITIES**

#### **Shares of Common Stock**

The Shares of Common Stock (the "Shares" or "Equity") have standard voting rights and are entitled to share in dividends when or if declared by the board of directors subordinate to any preferred shares and provided the Company's debts and other obligations have been satisfied and/or are current.

# **Voting Rights**

Shares of Common Stock have voting rights (i.e., one (1) vote per Share). For a more complete description of voting rights, see the Company's Bylaws attached hereto as an Exhibit.

#### **Revenue Interests in CZ48 Drug**

Share Subscribers in this Offering shall also be entitled to the assignment of a revenue interest in any future sales of the CZ48 Drug at the rate set forth in Schedule B of the attached Stock Purchase and CZ48 Drug Revenue Agreement (see the Exhibit section of this Offering Statement). If this Offering is fully subscribed for \$5,000,000, then up to approximately 30% of the Company's revenue interest in the CZ48 drug will be allocated accordingly directly to subscribers.

## **Other Securities**

We also reserve the right to issue securities of any kind at any time on terms other than the terms set forth in this Offering Statement.

### VALUATION

The Offering price for the securities offered pursuant to the Company's Form C and Offering Statement has been determined arbitrarily by the Company, and does not necessarily bear any relationship to the Company's book value, assets, earnings or other generally accepted valuation criteria.

The value of our Notes is likely based on the principal of the Note and no other valuation methodology. The return on investment for each Note is based on the creditworthiness of the Company and its ability to repay which is materially dependent upon successful execution of our business plan as well as other various market factors outside of the Company's control. The value of the Notes do not bear any relationship to the Company's book value, assets, earnings or other generally accepted valuation criteria.

# RISKS RELATED TO MINORITY OWNERSHIP IN THE COMPANY

#### Our officers, directors or key advisors may have conflicts of interest vis-à-vis the Company

There are conflicts of interest inherent in the activities of the Company. Our officers, directors and/or our key advisors or their Affiliates or personnel act in a similar capacity for other concerns within the pharmaceutical industry or elsewhere. Such persons intend to continue to manage such concerns and plan to do so in the future. Although we do not currently anticipate problems, any additional responsibilities taken on by such persons may cause them to devote less time to the business of the Company than is necessary or prudent. Also, many of our key personnel may receive equity in the Company.

Certain services to be provided to the Company, such as legal, accounting, marketing or consulting services, may be performed by Affiliates or personnel of the Company or related parties under common control. Also, our officers, directors and/or key advisors may collect fees, salaries, and/or related costs in connection with managing Company affairs paid out of the net proceeds of this

Offering. Consequently, there is the possibility that if the Company doesn't perform well, our officers, directors, key advisors or other personnel or related parties may still realize a profit even though the Company does not.

Conflicts of interest for the above-referenced persons and others associated with the Company by way of contract may also arise. Such individuals, either directly or indirectly, may provide services to other pharmaceutical companies and may acquire pharmaceutical assets for their own account and the account of others. In addition, such persons and/or their Affiliates are presently engaged in the pharmaceutical business independent of the Company and conduct such activities with other companies or private partners. Such persons may also be involved with pharmaceutical companies and in other aspects of private capital formation. All of these activities may result in conflicts of interest.

# RISKS RELATED TO CORPORATE ACTIONS, ISSUANCES OF ADDITIONAL SECURITIES, SALE OF THE COMPANY OR ITS ASSETS, ETC.

#### Transferability of Shares and/or CZ48 Drug Revenue Interests you purchase will be restricted

The Shares and/or CZ48 Drug Revenue Interests offered by way of this Offering Statement have not been registered with the Commission or any government's securities authority and will be restricted and therefore cannot be resold unless they are also registered or unless an exemption fr3om registration is available. Therefore, you should be prepared to hold the Shares for at least one (1) year and perhaps even an indefinite period of time.

# There is no liquidity associated with the Shares or CZ48 Drug Revenue Interests

Neither the Shares nor CZ48 Drug Revenue Interests will not be listed on any national securities exchange or included for quotation through an inter-dealer quotation system of a registered national securities association. The Shares and CZ48 Drug Revenue Interests constitute a new issue of securities with no established trading market. Furthermore, there can be no assurance that there will be any regular secondary market following the completion of the Offering. Therefore, an investment in these securities should be considered non-liquid. In addition, no assurance can be given that the initial Offering price for these securities will continue for any period of time.

#### We arbitrarily determined the Offering price of Shares and terms of CZ48 Drug Revenue Interests

The price per Share and the terms of the CZ48 Drug Revenue Interests bears no relationship to our assets, opportunities, net worth, or any recognized criteria of value and should not be considered to be an indication of the actual value of the Shares.

### MATERIAL TERMS OF THE COMPANY'S INDEBTEDNESS

Creditor(s)	Amount Outstanding	Interest Rate	Maturity Date	Other Material Terms
Accounts Payable (1)	See Footnote 1	See Footnote 1	See Footnote 1	See Footnote 1

Footnotes to table:

(1) (See Attached Financial Statements).

# OTHER EXEMPT OFFERINGS CONDUCTED BY THE COMPANY IN THE PAST THREE YEARS

Prior to (or concurrently with) the date on the cover of this Offering Statement certain of our Affiliates have conducted (or may be conducting) one or more private placement offerings of equity and/or debt securities on the same terms or on different terms as set forth in this Offering Statement. We believe the placement of such securities were conducted (or are being conducted) in compliance with existing U.S. federal and state securities laws and exemptions from registration. However, any one or more of such placements of such securities could be found by the SEC and/or one or more state securities regulatory agencies to have not been conducted in accordance with the requirements of available exemptions and/or constitute a single offering of securities,

which finding could lead to a disallowance of exemptions from registration. Such could give rise to various legal actions against our Affiliates brought by U.S. federal or state regulatory agencies and/or private litigants. In such event there can be no assurance that such proceedings would be settled in our favor or that such may not adversely affect us.

#### **RELATED-PARTY TRANSACTIONS**

Transactions between the Company and individuals or entities related to our principals can cause conflicts of interest to arise. Such related parties have interests that may differ in certain respects from our interests and those of yours. There can be no assurance that these relationships will withstand regulatory scrutiny. You should recognize that such relationships and transactions involve inherent conflicts between your interests and/or that of the Company and those of the parties related to our principals, and that the risk exists that we will not always resolve such conflicts in a manner that favors you or us. In addition, other transactions or dealings may arise in the future that could cause conflicts of interest. In our name or through our affiliated entities, and in connection with the operation of our various business activities, we have entered into or are otherwise party to contracts or transactions with related parties. See also, "Material Agreements", "Compensation", "Conflicts of Interest", and the footnotes of this Offering Statement. We may enter into similar contracts with other Affiliates from time to time. To review copies of any such contracts or agreements, please contact us. In some cases, a confidentiality agreement may be required as a condition.

### FINANCIAL CONDITION OF THE COMPANY

## **OPERATING HISTORY**

### Recent Milestones:

- 1. Phase 1 Clinical Trial Completed: In accordance with the Phase 1 protocol, we have had sufficient subjects to report to the FDA to conclude the Phase 1 study. The dosing 30 mg/m2, twice daily, appears safe for patient use, and we will prepare the Phase 2 study protocol using the dosage and schedule. The Phase 1 study was completed as of May 31, 2021, and we are working towards the completion and submission of the Phase 1 report to the FDA for approval.
- 2. <u>Pipeline products</u>: Three promising candidates have been intensely studied for their efficacies and toxicities in animals. Compared with Irinotecan, a commercially available anticancer drug in class, all these three candidates have more favorable therapeutic index. Currently, more preclinical data, such as, absorption, distribution, metabolism, and excretion, are being collected. One or two of these candidates will advance to GLP toxicity study, which will provide more data for filing IND to Food and Drug Administration (FDA).

For further information regarding our prior operating history and current activities, please contact us.

## DESCRIPTION OF FINANCIAL CONDITION OF THE COMPANY

You should read our financial statements and the related notes and other financial information included the Exhibit section of this Offering Statement. You also should review the "Business and Anticipated Business Plan" and "Risk Factors" sections of this Offering Statement for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by any forward-looking statements contained in this Offering Statement.

### FINANCIAL INFORMATION

Our Management has prepared reviewed financial statements for the Company through December 31, 2020. We believe such statements are materially correct. Such statements are included in the Exhibit section of this Offering Statement. In the event audited financial statements become available, this Offering Statement shall be amended and/or supplemented accordingly.

#### **OTHER MATERIAL INFORMATION**

#### SOURCES OF INFORMATION

This Offering Statement contains summaries of and references to certain documents which are believed to be accurate and reliable. Complete information concerning these documents is available for your inspection or your duly authorized financial consultants and advisors. All documents relating to the Company, our objectives and our current activities will be made available to you or your representatives at our offices by appointment. In some cases, a confidentiality agreement must be signed. Our Management is available by telephone or by appointment to provide answers to questions concerning our current plans. NO REPRESENTATIVE HAS BEEN AUTHORIZED TO GIVE YOU ANY INFORMATION OTHER THAN THAT SET FORTH IN THIS OFFERING STATEMENT.

# REPRESENTATIONS

This Offering Statement has been prepared to provide you with information concerning the risk factors, terms and proposed activities of the Company and to help you make an informed decision before subscribing for the Promissory Notes. However, neither the delivery of this Offering Statement to you nor any transaction made hereunder shall create any implication that there has been no change in our affairs since the date on the cover of this Offering Statement. Also, there are terms used throughout this Offering Statement which may be unfamiliar to some readers. Please refer to the definitions at the end of this Offering Statement.

Any clerical mistakes or errors in this Offering Statement are ministerial in nature and are not a material factual misrepresentation or a material omission of fact.

The Company has not retained independent counsel for prospective investors in this Offering. Attorneys assisting in the preparation of this Offering Statement represent only the Company and do not represent any individual Member, officer, manager, manager, investor, note Holder, or prospective investor.

This Offering Statement does not constitute an offer or solicitation to anyone in any state or jurisdiction in which such an offer or solicitation is not authorized. Any reproduction or distribution of this Offering Statement in whole or in part or the divulgence of any of its contents without our prior written consent is strictly prohibited. By accepting delivery hereof, you agree to return this Offering Statement and all associated documents to the Company to the address on the cover unless you subscribe for the Promissory Notes.

We reserve the right to withdraw this Offering in our sole discretion for any or no reason.

The Company's securities described in this Offering Statement are offered in reliance upon an exemption from registration under the U.S. Securities Act of 1933, as amended, and other applicable U.S. federal and state law exemptions. Accordingly, the Promissory Notes are deemed "restricted securities" as such term is defined under U.S. federal and state securities laws, and cannot be subsequently sold or transferred without registration or reliance, to the satisfaction of counsel for the Company, that an exemption from registration is available. You should be aware that no market for the Promissory Notes presently exists and there can be no assurance that a market will ever materialize.

We are not registered as an "investment company" as such term is defined under the Investment Company Act of 1940, as amended. To the extent such statute applies to us, if at all, we are relying upon exemptions available to companies under Section 3(c)(1) of the Investment Company Act of 1940, as amended, and other applicable U.S. federal and state law exemptions.

We are not currently subject to ongoing information disclosure requirements of the Securities and Exchange Act of 1934, as amended, and most likely will not be subject to such requirements after the completion of this Offering. Accordingly, we are not required to provide annual reports. However, we plan to keep investors apprised of the Company's activities and progress from time to time.

This Offering Statement does not purport to be complete. Throughout this Offering Statement reference is made to certain information not contained in this document. If you wish to read the referenced material, we will attempt to provide it for you so long as procuring such information is not unduly expensive or burdensome. Please call us at our main telephone number (see cover page) to inquire about referenced information.

#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the information in this Offering Statement may contain forward-looking statements. Such statements include, in particular, statements about our plans, strategies and prospects. You can generally identify forward-looking statements by our use of forward-looking terminology such as "may", "will", expect", "intend", "anticipate", "estimate", "believe", "continue", or other similar words. Although we believe that our plans, intentions and expectations reflected in such forward-looking statements are reasonable, you should not rely upon our forward-looking statements because the matters they describe are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond our control. These forward-looking statements are subject to various risks and uncertainties, including, but not limited to, those discussed above under "Risk Factors", that could cause our actual results to differ materially from those projected in any forward-looking statement we make. We do not anticipate to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

# **COMPETITION**

The pharmaceutical industry is highly competitive. The principal competitive factors in the pharmaceutical market include:

- Introduction of other generic drug manufacturers' products in direct competition with our generic drug products;
- Introduction of authorized generic drug products in direct competition with our products, particularly during exclusivity periods;
- The ability of generic drug product competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits;
- Consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups;
- The willingness of generic drug customers, including wholesale and retail customers, to switch among products of different pharmaceutical manufacturers;
- Pricing pressures by competitors and customers;
- A company's reputation as a manufacturer and distributor of quality products;
- A company's level of service (including maintaining sufficient inventory levels for timely deliveries);
- Product appearance and labeling; and
- A company's breadth of product offerings.

Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than us. Consequently, some of our competitors may be able to develop products and/or processes competitive with, or superior to, our products. Furthermore, we may not be able to (i) differentiate our products from those of our competitors, (ii) successfully develop or introduce new products on a timely basis or at all that are less costly than those of our competitors, or (iii) offer customers payment and other commercial terms as favorable as those offered by our competitors. The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant change. We expect

competition to intensify as technological advances and consolidation continues. New developments by other manufacturers and distributors could render our products uncompetitive or obsolete.

We also face price competition generally as other generic manufacturers enter the market. Any such price competition may be especially pronounced where our competitors source their products from jurisdictions where production costs may be lower (sometimes significantly) than our production costs, especially lower-cost foreign jurisdictions. Any of these factors could result in reductions in our sales prices and gross margin. This price competition has led to an increase in demands for downward price adjustments by generic pharmaceutical distributors. Our principal strategy in addressing our competition is to offer customers a consistent supply of our generic drug products, as well as to pursue product opportunities with the potential for limited competition, such as high-barrier-to-entry first-to-file or first-to-market products. There can be no assurance, however, that this strategy will enable us to compete successfully in the generic drug product industry or that we will be able to develop and implement any new or additional viable strategies.

Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. Authorized generic drug products are generic drug products that are introduced by brand companies, either directly or through third parties, under the brand's New Drug Application ("NDA") approval for our own branded drug. Authorized generics do not face any regulatory barriers to introduction and are not prohibited from sale during the 180-day marketing exclusivity period granted to the FTF ANDA applicant. The sale of authorized generics adversely impacts the market share of a generic drug product that has been granted 180 days of marketing exclusivity. This is a significant source of competition for us, because an authorized generic drug product. Such actions have the effect of reducing the potential market share and profitability of our generic drug products and may inhibit us from developing and introducing generic pharmaceutical drug products corresponding to certain branded drugs.

### **DESCRIPTION OF PROPERTY**

We currently lease office space located in Webster, Texas, USA.

#### MATERIAL AGREEMENTS

The Company has entered into, will enter into, and/or is otherwise a party to various material contracts with Affiliates and/or third parties. We will make copies of all such contracts available to you for inspection at our corporate offices in Webster, Texas, at normal business hours or via electronic file sharing upon reasonable request. In some cases, some agreements may be redacted or withheld. We may also require you to enter into a confidentiality agreement as a condition. Also, subsequent to the date of this Offering Statement, we may enter into one or more side letters with Members. "Side letters" mean any informal written agreement or letter of understanding entered into by the Company with one or more Members or other Persons which may materially obligate the Company and/or modify the terms of this Offering, a Member's Stock Purchase Agreement, Units, Notes, and/or rights and obligations under the Operating Agreement, or entitle such Member or other Person to rights and/or preferences which may be materially different than the terms contemplated by this Offering Statement. The Company is under no obligation to supplement this Offering Statement with a description of any future side letters to which it may become a party.

### COMPENSATION

Our Management and/or their Affiliates will be paid in connection with their management and administration of Company affairs. Such persons are also eligible for reimbursement for general and administrative costs and expenses, including, but not limited to, travel, legal, accounting, overhead, due diligence, market research, and pre-acquisition research costs and other expenses in connection with the pursuit of the Company's objectives (See "Estimated Use of Proceeds"). Such persons may receive salaries and equity or other forms of compensation out of the proceeds of this Offering or from our revenue, capital, or other Company assets for services performed on behalf of the Company. Such services may include, but are not limited to, legal, accounting, marketing, overhead, investor relations, communications, administrative support, etc. Such compensation terms may not have been negotiated at arms-length. See "Conflicts of Interest". Other substantial and material compensation terms may be negotiated with Management, other persons, advisors, consultants, new hires, etc., subsequent to the date on the cover of this Offering Statement (See "Conflicts of Interest"). For updated compensation terms of our Management, please contact us.

Cao Pharmaceuticals Inc.

### REGULATION CROWDFUNDING OFFERING STATEMENT

### **CONFLICTS OF INTEREST**

Our Management may act in a similar capacity for other unaffiliated concerns. Our Management's capability to satisfy its obligations to the Company could be adversely affected by such other involvements. Certain services to be provided to the Company, such as legal, accounting, engineering, analysis, consulting, marketing, and technical services may be performed by Affiliates or related parties of the Company's Management. While such services are expected to be performed at rates believed to be comparable to rates charged by other independent non-affiliated concerns for similar services, there can be no assurance of this. Also, there is the likelihood that if our anticipated activities are not ultimately profitable, that such Affiliates or related parties may still realize profits even though you do not realize the same such profit. Conflicts of interest may arise for our Management, consultants, Affiliates, and others associated with the Company by way of contract. Such individuals, either directly or indirectly, may provide like services to other concerns. In addition, certain consultants, advisors, and members of our key personnel, Management, and their Affiliates are presently engaged in other companies or ventures. See also, "Material Agreements", "Compensation", and "Related Party Transactions".

Each of our Management team may be engaged in other business endeavors, may commit themselves to other entities, and are not obligated to work full time on the Company's affairs. For example, our Management are actively involved in numerous other pharmaceutical or drug manufacturing business concerns, some of which operate out of the same office space utilized by the Company. If the other business affairs of our Management require them to devote more substantial amounts of time to such affairs, it could limit their ability to devote time to the affairs of the Company, which could have a negative impact on our ability to operate efficiently.

In addition, our Management may become affiliated with other entities engaged in pharmaceutical or drug manufacturing businesses. Additionally, our Management may become aware of business opportunities which may be appropriate for presentation to the Company as well as the other entities with which they are or may be affiliated. Due to their existing affiliations, our Management may have fiduciary obligations to present potential business opportunities to those entities before presenting them to us, which could cause additional conflicts of interest. We cannot assure you that these conflicts will be resolved in our favor.

Also, certain personnel may have personal or family relationships with each other. Such non-business relationships could give rise to issues not otherwise present.

Our Management will be indemnified by the Company and authorized to obtain D&O (directors and officers) liability insurance paid for by the Company.

All of these activities and factors may result in conflicts of interest.

#### CERTAIN U.S. INCOME TAX CONSIDERATIONS

TO ENSURE COMPLIANCE WITH TREASURY DEPARTMENT CIRCULAR 230, INVESTORS ARE HEREBY NOTIFIED THAT (A) ANY DISCUSSION OF FEDERAL TAX ISSUES IN THIS OFFERING STATEMENT IS NOT INTENDED OR WRITTEN TO BE RELIED UPON, AND CANNOT BE RELIED UPON, BY INVESTORS FOR THE PURPOSE OF AVOIDING PENALTIES THAT MAY BE IMPOSED ON INVESTORS UNDER THE INTERNAL REVENUE CODE; (B) SUCH DISCUSSION IS INCLUDED HEREIN BY OUR COMPANY IN CONNECTION WITH THE PROMOTION OR MARKETING (WITHIN THE MEANING OF CIRCULAR 230) BY THE COMPANY OF THE TRANSACTIONS OR MATTERS ADDRESSED HEREIN; AND (C) INVESTORS SHOULD SEEK ADVICE BASED ON THEIR PARTICULAR CIRCUMSTANCES FROM AN INDEPENDENT TAX ADVISOR.

IF YOU ARE CONSIDERING SUBSCRIBING FOR THIS OFFERING, WE URGE YOU TO CONSULT YOUR OWN TAX ADVISORS CONCERNING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO YOU OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR SECURITIES, AS WELL AS ANY CONSEQUENCES TO YOU ARISING UNDER STATE, LOCAL, AND NON-U.S. TAX LAWS.

# PROSPECTIVE INVESTORS SHOULD ONLY CONSIDER AN INVESTMENT IN OUR COMPANY BASED ON REASONS INDEPENDENT OF THE TAX CONSEQUENCES OF SUCH INVESTMENT. TAX ADVANTAGES (I.E., DEDUCTIONS AND LOSSES) ARE NOT A SIGNIFICANT OR INTENDED FEATURE OF AN INVESTMENT IN OUR COMPANY.

We are a "C-corp" for tax purposes. Neither we nor our Management, advisors, lawyers, accountants, or other representatives make any representation or otherwise provide any tax advice concerning acquiring our Securities. By acquiring our Securities, you represent and warrant that you have consulted your own tax advisor concerning our Securities and you are not relying upon us or any of the other persons listed in this paragraph, above.

#### LEGAL PROCEEDINGS

As of the date of this Offering Statement, we are not a party to any litigation. The Company and/or its Affiliates may be or become parties to litigation in the normal course of business or may be or become subject to government investigations or administrative proceedings from time to time. In any event, we do not believe that such matters will have a material adverse effect on our business, financial condition or results of operations. We are presently unaware of any active material legal proceedings, regulatory or otherwise, against the Company or its Affiliates that may have a material impact on our prospective activities.

#### DILUTION

"Dilution" represents the difference between the Offering price of an equity security and the net book value of such security. "Net book value" is typically the amount that results from subtracting the total liabilities of a company from its total assets. Our most recent available financial statements (unaudited) are included in the Exhibit section of this Offering Statement. Presuming placement of all Shares offered hereby (which may or may not occur), and presuming no issuance of any new debt and with combined assets (See "Capitalization and Indebtedness"), and presuming no material change in our net book value between the date of such financial statements and the date of this Offering Statement, you'll likely suffer significant and material dilution per Share you purchase in this Offering. Initial investors in the Offering will be exposed to greater risk of dilution. You may suffer significant and material dilution while our Management, founders, and others may receive a corresponding beneficial increase in the value of Shares held by them. Also, our Board may adopt an Equity Incentive Plan in the future through which options, stock awards, or other equity incentives may be issued to Company employees, personnel, advisors, and/or our Management on terms to be determined. In the event options, stock awards, or other equity incentives are issued and/or exercised, such will have a material dilutive effect upon your ownership in the Company. Subsequent to or concurrent with the closing of this Offering we may seek to raise additional capital through the issuance of additional debt or equity to new investors on terms that may be different from the terms set forth in this Offering Statement. Such issuance of new equity and/or debt securities by the Company would likely have a further material dilutive effect upon your ownership in the Company. (See "Capitalization and Indebtedness", "Compensation", and "Conflicts of Interest").

#### **ONGOING REPORTING**

The Company will file a report with the Commission annually and post the report on its website, no later than 120 days after the end of each fiscal year covered by the report.

The Company may terminate its reporting obligations in the future in accordance with Rule 202(b) of Regulation Crowdfunding in the event:

- (1) the Company is required to file reports under Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended (the "Exchange Act");
- (2) the Company has filed, since its most recent sale of securities pursuant to Regulation Crowdfunding, at least one annual report pursuant to Regulation Crowdfunding and has fewer than 300 holders of record;

- (3) the Company has filed, since its most recent sale of securities pursuant to Regulation Crowdfunding, the annual reports required pursuant to Regulation Crowdfunding for at least the three most recent years and has total assets that do not exceed USD \$10,000,000;
- (4) the Company or another party repurchases all of the Securities issued in reliance on Section 4(a)(6) of the Securities Act including any payment in full of debt securities or any complete redemption of redeemable securities; or
- (5) the Company liquidates or dissolves its business in accordance with state law.
- The Company's filings and reports pursuant to Regulation Crowdfunding may be viewed online at www.sec.gov.

If you or your advisors would like additional information regarding the Company or our objectives, please contact us:

Cao Pharmaceuticals Inc. 17490 Hwy. 3, Suite B200 Webster, Texas 77598 USA Telephone: 281-253-3891 E-mail: chrisw@caopharmaceuticals.com

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# EXHIBIT A

# COPY OF ARTICLES OF INCORPORATION



Cao Pharmaceuticals Inc. 17490 Hwy. 3, Suite B200 Webster, Texas 77598 USA Telephone: 281-253-3891 E-mail: chrisw@caopharmaceuticals.com

This section alone does not constitute an offer by the Company or its Affiliates. An offer may be made only by an authorized representative of the Company and the recipient must receive a complete Offering Statement, including all Exhibits.

EXHIBIT B

# COPY OF BYLAWS



Cao Pharmaceuticals Inc. 17490 Hwy. 3, Suite B200 Webster, Texas 77598 USA Telephone: 281-253-3891 E-mail: chrisw@caopharmaceuticals.com

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## Cao Pharmaceuticals Inc.

# R E G U L A T I O N C R O W D F U N D I N G O F F E R I N G S T A T E M E N T

# EXHIBIT C

# FINANCIAL INFORMATION



Cao Pharmaceuticals Inc. 17490 Hwy. 3, Suite B200 Webster, Texas 77598 USA Telephone: 281-253-3891 E-mail: chrisw@caopharmaceuticals.com

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# EXHIBIT D

# FORM OF STOCK PURCHASE AND CZ48 DRUG REVENUE AGREEMENT



Cao Pharmaceuticals Inc. 17490 Hwy. 3, Suite B200 Webster, Texas 77598 USA Telephone: 281-253-3891 E-mail: chrisw@caopharmaceuticals.com

This section alone does not constitute an offer by the Company or its Affiliates. An offer may be made only by an authorized representative of the Company and the recipient must receive a complete Offering Statement, including all Exhibits.



# STOCK PURCHASE AND CZ48 DRUG REVENUE AGREEMENT

This Stock Purchase and CZ48 Drug Revenue Agreement (the "Agreement") is the definitive agreement related to the purchase of Cao Pharmaceuticals Inc. shares of common stock (the "Shares" or "CPI stock") and revenue percentage of the drug CZ48 ("CZ48" or the "drug") as described below between

Both the Seller and the Purchaser agree to be bound by this Agreement.

Purchaser will obtain CPI share ownership and CZ48 drug revenue interest percentages as listed in Schedules A and B and in accordance with the Seller's Offering Statement dated April 19, 2022 (the "Offering Statement") which Offering Statement is incorporated into this Agreement by reference.

Although the drug CZ48 is wholly owned by CPI, this Agreement defines revenue from this drug as a distinct and separate asset from CPI stock. Any and all revenue from CZ48 will be financially reported as a separate carve-out and be dispersed as described below.

WHEREAS, the Seller desires to sell the percentage ownership of CPI stock to the Purchaser and the Purchaser agrees to purchase the stock from the Seller subject to the terms and conditions herein, and

WHEREAS, the Seller desires to sell revenue percentage of the drug, CZ48 (chemically known as Camptothecin-20-O-Propionate hydrate), with US and non-US patent owned by Seller, to the Purchaser and the Purchaser agrees to purchase a revenue percentage of CZ48 from the Seller subject to the terms and conditions herein.

NOW, THEREFORE, in consideration of the mutual covenants and promises made by the parties hereto, the Purchaser and the Seller (individually, each a "Party" and collectively, the "Parties") covenant and agree as follows.

1. **PURCHASE AND SALE**. Subject to the terms and conditions of this Stock Purchase and CZ48 Drug Revenue Agreement, the Seller agrees to sell to the Purchaser, and the Purchaser agrees to purchase from the Seller, shares of CPI stock (the "Shares") according to Schedule A attached to this Agreement, which is incorporated into this Agreement by reference, and

The Seller agrees to assign revenue percentage of the CZ48 drug according to Schedule B attached to this Agreement which is incorporated into this Agreement by reference.

The number of CPI shares will be increased according to the aggregate syndicate investment and timeline (Milestone) as defined in Schedule A. If a successive milestone is reached after the signing of this Agreement, an amended Agreement based on the Schedule B will be executed in a timely manner. If the conditions of any single Milestone are not met, the remaining Milestones are rendered void. These Milestone dates can only be extended if approved in writing by CPI, and in which case the modifications will be communicated to each Syndicate Investor.

- 3. **EXECUTION AND DELIVERY**. Upon the execution and delivery of this Agreement, the Seller shall deliver to the Purchaser any documentation the Company reasonably requires to process the transfer of the revenue percentage of CZ48 and CPI Shares to the Purchaser. All documentation shall be delivered to the Purchaser within 180 days of the full execution of this Agreement or amended Agreement (the "Closing Date").
- 4. **SELLER'S REPRESENTATIONS.** The Seller represents, warrants, and agrees to and with the Purchaser as follows as of the date of execution of this Agreement and on the Closing Date.
  - a. CPI is a corporation duly formed and organized under the laws of Texas;
  - b. CPI is in good standing under the laws of Texas and requires no action by the Purchaser to achieve compliance;
  - c. There is no proceeding, claim or investigation pending against CPI or any of its subsidiaries by any third party or governmental agency, nor, to the Seller's knowledge, has any such claim or investigation been threatened;
  - d. The Seller is the sole beneficial, legal, and record owner of the Shares;
  - e. The Seller holds valid and marketable title to the Shares which are free and clear of all encumbrances, restrictions on transfer, or other defects in title of any kind;
  - f. The Seller has the right and authority to enter into and carry out the terms of this Agreement, including without limitation, the offer, sale, and transfer of the Shares to the Purchaser and has taken all action necessary to validly do so; and
  - g. The Seller is not a party to any contract that remains in effect with respect to the Shares and there are no restrictions on the offer, sale, or transfer of the Shares other than applicable securities laws.
- 5. **EXPENSES**. Each respective Party will pay all expenses and fees of his or its legal counsel, accountants, and other agents and advisers incurred pursuant to this Agreement regardless of whether the transactions contemplated in this Agreement are consummated.
- 6. **INDEMNIFICATION**. The Purchaser and the Seller each hereby agree to defend, indemnify and hold harmless the other from and against any claim, damage, liability, loss, cost or expense (including reasonable attorney's fees) arising directly or indirectly out of:
  - a. Any failure to perform obligations set forth in this Agreement;
  - b. Any inaccuracy or breach of warranties made in this Agreement, and any and all actions, suits, litigation, arbitration, proceedings, investigations, claims or liabilities of whatever nature arising out of any of the foregoing.

Seller further agrees to defend, indemnify and hold Purchaser harmless from and against any claims, damages, liabilities, losses, costs or expenses (including reasonable attorney's fees) arising directly or indirectly out of the drug CZ48, and/or the business operations or affairs of Seller and/or the Syndicate. The foregoing indemnities shall survive this Agreement.

# 7. PURCHASER RIGHTS AND REPRESENTATIONS:

- a. Purchaser affirms that they are an accredited investor and/or they otherwise qualify to invest in the Company's securities under and pursuant to the requirements of Regulation Crowdfunding and understands that all capital invested is at risk.
- b. Purchaser ownership of CPI shares and CZ48 revenue percentage can be transferred to legal heirs.
- c. Resale by the Purchaser of all or partial ownership of CPI percentage stock and/or CZ48 revenue percentage must be in the following order of Right of First Refusal to match any written offer; 1<sup>st</sup> to Cao Pharmaceutical Inc. principals, 2nd to other Syndicate members, and 3<sup>rd</sup> to outside parties.
- d. Purchaser will pay for administrative fees for any ownership transfer.
- e. Purchaser agrees to make a good faith effort to resolve any disagreements.
- 8. NO MODIFICATION UNLESS IN WRITING. No modification of this Agreement shall be valid unless in writing and agreed upon by both Parties.

9. **VENUE**. This Stock Purchase and CZ48 Drug Revenue Agreement and the interpretation of the terms herein shall be governed by and construed in accordance with the laws of the State of Texas. The Parties irrevocably submit to the exclusive jurisdiction of the federal and state courts located in Harris County, Texas.

IN WITNESS WHEREOF, each of the Parties has executed this Stock Purchase and CZ48 Drug Revenue Agreement electronically or in person, both Parties by its duly authorized officer, as of the day and year set forth below.

# **PURCHASER:**

X	X
Authorized Signature	Second Authorized Signature (if applicable)
Print Name	Print Name
Date	Date
Title (if applicable)	Title (if applicable)
Name of Entity (if applicable)	Name of Entity (if applicable)
SELLER:	
Cao Pharmaceuticals Inc. a Texas corporation	
By:	Acceptance Date:
Name:	Title:

Milestone	1	2	3	4	5	6
Investment Amount	\$0-2M	>2M - 4M	\$ > 4M - 6M	\$> 6M - 8M	\$> 8M - 10M	\$> 10M - 12M
CPI % received	0.20% / \$1M	0.4% / \$1M	0.6% / \$1M	0.8% / \$1M	1.0% / \$1M	1.2% / \$1M
Total CPI share	0-0.4%	> 0.8 - 1.6%	> 2.4 - 3.6%	>4.8-6.4%	>8.0-10.0%	>12.0 - 14.4%
Price per Share	\$500.00	\$250	\$166.67	\$125	\$100	\$83.33

Milestone	7	8
Investment	\$12.0 - 14.0M	\$ >14.0 -
Amount		16M
CPI %	1.4% / \$1M	1.6% / \$1M
received		
Total CPI	>16.8 - 19.6%	> 22.4 -
share		25.6%
Price per	\$71.43	\$62.50
Share		

Note: All investors will pay the same price per share because additional shares will be credited to existing investors as new investors enter and next milestones are achieved.

Investment Amount	Revenue % per \$1M	Total Revenue %
Up to \$9M	6% per \$1M	Up to 54.0%
From \$9M - \$16M	1.14% per \$1M	From 54.0% up to 62.0%

\* The additional \$7M (\$2.33M for each Phase IIb) investment will be needed if the statistical analysis of Phase IIA is positive to fund the Phase IIb. These funds receive lower share amounts as the risk for licensing of CZ48 has been greatly reduced by the positive statistical interim analysis of Phase IIA. Investors that comprise the initial \$9M funding will have right of first refusal to participate on a proportionate basis for each Phase IIb study.