Squarex Pharmaceutical Corporation

5,000,000 shares of Common Stock

$3.00 per share

PRIVATE PLACEMENT MEMORANDUM

The information contained in this Memorandum was obtained from Squarex Pharmaceutical Corporation (the "Company") and from other sources. Any estimates, projections or other forward-looking statements contained in this Memorandum or otherwise made available to potential investors have been prepared by the management of the Company in good faith on a basis it believes is reasonable. Such estimates, projections and other forward-looking statements involve significant elements of subjective judgment and analysis, and no representation can be made as to their attainability. The Company does not make any representation or warranty (express or implied) as to the accuracy or completeness of the information contained in this Memorandum, and nothing contained herein is, or shall be relied upon as a promise or representation, whether as to the past or the future performance of the Company. This Memorandum does not purport to contain all of the information that may be required to evaluate an investment in the Company, and any recipient hereof should conduct its own independent analysis of the Company and the data contained or referred to herein. The Company does not expect to update or otherwise revise this Memorandum or other materials supplied herewith.

May 31, 2023

TABLE OF CONTENTS

You should rely only on the information contained in this memorandum or in any free writing memorandum that we may specifically authorize to be delivered or made available to you. We have not authorized anyone to provide you with any information other than that contained in this memorandum or in any free writing memorandum we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This memorandum may only be used where it is legal to offer and sell our securities. The information in this memorandum is accurate only as of the date of this memorandum, regardless of the time of delivery of this memorandum or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not making an offer of these securities in any jurisdiction where the offer is not permitted.

NOTICES TO INVESTORS

EACH PROSPECTIVE INVESTOR, BY ACCEPTING A COPY OF THIS MEMORANDUM, ACKNOWLEDGES THAT SUCH INVESTOR MAY RECEIVE CONFIDENTIAL INFORMATION FROM US, AND AGREES NOT TO DISCLOSE ANY SUCH CONFIDENTIAL INFORMATION TO OTHERS, AND TO USE SUCH CONFIDENTIAL INFORMATION ONLY TO EVALUATE AN INVESTMENT IN THE SECURITIES OFFERED HEREBY AND NOT FOR ANY OTHER PURPOSE.

INVESTORS ARE UNDER NO OBLIGATION TO PARTICIPATE IN THIS PRIVATE OFFERING. BY ACCEPTING A COPY OF THIS MEMORANDUM, INVESTORS DO NOT AGREE TO PARTICIPATE IN THIS PRIVATE OFFERING. INVESTORS ARE ENCOURAGED TO CAREFULLY REVIEW THIS MEMORANDUM AND ALL OF THE DOCUMENTS ATTACHED AS EXHIBITS HERETO BEFORE AGREEING TO PARTICIPATE IN THIS OFFERING.

THIS MEMORANDUM HAS BEEN PREPARED IN CONNECTION WITH A PRIVATE OFFERING OF SECURITIES BY THE COMPANY. THE INFORMATION IN THIS MEMORANDUM IS PROVIDED ONLY TO ACCREDITED INVESTORS HAVING THE ABILITY TO ACCEPT THE RISKS AND LACK OF LIQUIDITY INHERENT IN THE PROPOSED INVESTMENT.

THIS OFFERING IS BEING MADE IN RELIANCE ON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT") AND CERTAIN STATE SECURITIES LAWS AS AN OFFER AND SALE OF SECURITIES NOT INVOLVING A PUBLIC OFFERING. NO ASSURANCE CAN BE GIVEN THAT A PUBLIC MARKET WILL DEVELOP FOR THE COMMON STOCK. THE SECURITIES MAY NOT BE TRANSFERRED WITHOUT SATISFACTION OF CERTAIN CONDITIONS, INCLUDING REGISTRATION OR THE AVAILABILITY OF AN EXEMPTION UNDER THE SECURITIES ACT AND THE SECURITIES LAWS OF CERTAIN STATES. PROSPECTIVE INVESTORS SHOULD ASSUME THAT THEY MAY HAVE TO BEAR THE ECONOMIC RISK OF AN INVESTMENT IN THE SECURITIES FOR AN INDEFINITE PERIOD OF TIME.

THE SECURITIES ARE BEING OFFERED HEREBY WITHOUT REGISTRATION UNDER THE SECURITIES ACT BY REASON OF THE EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT SET FORTH IN SECTION 4(2) THEREOF AND RULE 506 OF REGULATION D PROMULGATED THEREUNDER ("RULE 506"). RULE 506 SETS FORTH CERTAIN RESTRICTIONS AS TO THE NUMBER AND NATURE OF PURCHASERS OF SECURITIES OFFERED PURSUANT THERETO. WE HAVE ELECTED TO SELL SECURITIES ONLY TO ACCREDITED INVESTORS, AS SUCH TERM IS DEFINED IN RULE 501(A) OF REGULATION D ("ACCREDITED INVESTORS"). EACH PROSPECTIVE INVESTOR WILL BE REQUIRED TO MAKE REPRESENTATIONS AS TO THE BASIS UPON WHICH IT QUALIFIES AS AN ACCREDITED INVESTOR.

THIS OFFERING IS MADE SUBJECT TO WITHDRAWAL, CANCELLATION OR MODIFICATION BY US. WE RESERVE THE RIGHT TO REJECT ANY SUBSCRIPTION IN WHOLE OR IN PART OR TO ALLOT TO ANY PROSPECTIVE INVESTOR FEWER THAN THE NUMBER OF SECURITIES SUBSCRIBED FOR BY SUCH INVESTOR. THE SECURITIES WILL BE SOLD ONLY TO A LIMITED NUMBER OF INVESTORS MEETING CERTAIN STANDARDS.

THIS MEMORANDUM IS CONFIDENTIAL AND HAS BEEN PREPARED BY THE COMPANY SOLELY FOR USE IN CONNECTION WITH THE PROPOSED OFFERING DESCRIBED HEREIN. THIS MEMORANDUM IS PERSONAL TO EACH OFFEREE AND DOES NOT CONSTITUTE AN OFFER TO ANY OTHER PERSON OR TO THE PUBLIC GENERALLY TO SUBSCRIBE FOR OR OTHERWISE ACQUIRE THE SECURITIES. DISTRIBUTION OF THIS MEMORANDUM TO ANY PERSON OTHER THAN THE OFFEREE AND THOSE PERSONS, IF ANY, RETAINED TO ADVISE SUCH OFFEREE WITH RESPECT THERETO IS UNAUTHORIZED. ANY DISCLOSURE OF ANY OF ITS CONTENTS, WITHOUT PRIOR WRITTEN CONSENT OF US, IS PROHIBITED. EACH PROSPECTIVE INVESTOR, BY ACCEPTING A COPY OF THIS MEMORANDUM, AGREES TO THE FOREGOING AND TO MAKE NO REPRODUCTION OF THIS MEMORANDUM OR ANY DOCUMENTS REFERRED TO HEREIN.

BY ACCEPTING DELIVERY OF ANY OFFERING MATERIAL, THE OFFEREE AGREES (I) TO KEEP CONFIDENTIAL THE CONTENTS THEREOF AND NOT TO DISCLOSE THE SAME TO ANY THIRD PARTY OR OTHERWISE USE THE SAME FOR ANY PURPOSE OTHER THAN EVALUATION BY SUCH OFFEREE OF A POTENTIAL PRIVATE INVESTMENT IN THE COMPANY, AND (II) TO RETURN THE SAME TO THE COMPANY IF (A) THE OFFEREE DOES NOT SUBSCRIBE TO PURCHASE ANY SECURITIES, (B) THE OFFEREE'S SUBSCRIPTION IS NOT ACCEPTED, OR (C) THE OFFERING IS TERMINATED OR WITHDRAWN.

CERTAIN PROVISIONS OF VARIOUS AGREEMENTS ARE SUMMARIZED IN THIS MEMORANDUM, BUT PROSPECTIVE INVESTORS SHOULD NOT ASSUME THAT THE SUMMARIES ARE COMPLETE. SUCH SUMMARIES ARE QUALIFIED IN THEIR ENTIRETY BY REFERENCE TO THE TEXTS OF THE COMPLETE DOCUMENTS.

IN DECIDING WHETHER TO PURCHASE SECURITIES, EACH INVESTOR MUST CONDUCT AND RELY ON ITS OWN EVALUATION OF THE COMPANY AND THE TERMS OF THE OFFERING, INCLUDING THE MERITS AND RISKS INVOLVED IN MAKING AN INVESTMENT DECISION WITH RESPECT TO THE SECURITIES. PROSPECTIVE INVESTORS SHOULD NOT CONSTRUE THE CONTENTS OF THIS MEMORANDUM OR ANY PRIOR OR SUBSEQUENT COMMUNICATIONS FROM THE COMPANY, OR ANY PROFESSIONAL ASSOCIATED WITH THE OFFERING, AS LEGAL OR TAX ADVICE. THE OFFEREE AUTHORIZED TO RECEIVE THIS MEMORANDUM SHOULD CONSULT ITS OWN TAX COUNSEL, ACCOUNTANT OR BUSINESS ADVISOR, RESPECTIVELY, AS TO LEGAL, TAX AND RELATED MATTERS CONCERNING ITS PURCHASE OF THE SECURITIES.

EXCEPT AS OTHERWISE INDICATED, THIS MEMORANDUM SPEAKS AS OF THE DATE HEREOF. NEITHER THE DELIVERY OF THIS MEMORANDUM NOR ANY SALE MADE HEREUNDER SHALL, UNDER ANY CIRCUMSTANCES, CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN THE AFFAIRS OF THE COMPANY AFTER THE DATE HEREOF. THE COMPANY MAKES NO WARRANTY TO UPDATE THIS MEMORANDUM.

WE WILL MAKE AVAILABLE TO ANY PROSPECTIVE INVESTOR, PRIOR TO EACH CLOSING, THE OPPORTUNITY TO ASK QUESTIONS OF AND TO RECEIVE ANSWERS FROM OUR REPRESENTATIVES CONCERNING US AND THE TERMS AND CONDITIONS OF THE OFFERING AND TO OBTAIN ANY ADDITIONAL RELEVANT INFORMATION TO THE EXTENT WE POSSESS SUCH INFORMATION OR CAN OBTAIN IT WITHOUT UNREASONABLE EFFORT OR EXPENSE.

THE SECURITIES DESCRIBED HEREIN MAY NOT BE SOLD NOR MAY ANY OFFERS TO PURCHASE BE ACCEPTED PRIOR TO THE DELIVERY TO PROSPECTIVE INVESTORS OF CERTAIN UNDERLYING DOCUMENTS INCLUDING, AMONG OTHER THINGS, A PROPOSED SECURITIES PURCHASE AGREEMENT REFLECTING THE DEFINITIVE TERMS AND CONDITIONS OF THE OFFERING. THE FULL TEXT OF SUCH PROPOSED SECURITIES PURCHASE AGREEMENT SHOULD BE REVIEWED CAREFULLY PRIOR TO PURCHASE.

WE RESERVE THE RIGHT, IN OUR SOLE DISCRETION AND FOR ANY REASON WHATSOEVER, TO MODIFY, AMEND AND/OR WITHDRAW ALL OR A PORTION OF THE OFFERING AND/OR TO ACCEPT OR REJECT IN WHOLE OR IN PART ANY PROSPECTIVE INVESTMENT IN THE SECURITIES OR TO ALLOT TO ANY PROSPECTIVE INVESTOR LESS THAN THE NUMBER OF SECURITIES SUCH INVESTOR DESIRES TO PURCHASE. WE SHALL HAVE NO LIABILITY WHATSOEVER TO ANY OFFEREE AND/OR INVESTOR IN THE EVENT THAT ANY OF THE FOREGOING SHALL OCCUR.

THIS MEMORANDUM (TOGETHER WITH ANY AMENDMENTS OR SUPPLEMENTS AND ANY OTHER INFORMATION THAT MAY BE FURNISHED TO PROSPECTIVE INVESTORS BY US) INCLUDES OR MAY INCLUDE CERTAIN STATEMENTS, ESTIMATES AND FORWARD-LOOKING PROJECTIONS OF THE COMPANY WITH RESPECT TO THE ANTICIPATED FUTURE PERFORMANCE OF THE COMPANY. SUCH STATEMENTS, ESTIMATES AND FORWARD-

LOOKING PROJECTIONS REFLECT VARIOUS ASSUMPTIONS OF MANAGEMENT THAT MAY OR MAY NOT PROVE TO BE CORRECT AND INVOLVE VARIOUS RISKS AND UNCERTAINTIES.

THIS MEMORANDUM DOES NOT PURPORT TO BE ALL-INCLUSIVE OR CONTAIN ALL INFORMATION THAT A PROSPECTIVE INVESTOR MAY DESIRE IN INVESTIGATING US. 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. INVESTORS SHOULD BE AWARE THAT THEY MAY BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME.

THIS MEMORANDUM AND SECURITIES PURCHASE AGREEMENT CONTAINS ALL OF THE REPRESENTATIONS BY US CONCERNING THIS OFFERING, AND NO PERSON IS AUTHORIZED TO MAKE DIFFERENT OR BROADER STATEMENTS THAN THOSE CONTAINED HEREIN. INVESTORS ARE CAUTIONED NOT TO RELY UPON ANY INFORMATION NOT EXPRESSLY SET FORTH IN THIS MEMORANDUM.

NO BROKER, DEALER, SALESMAN OR OTHER PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATION NOT CONTAINED IN THIS MEMORANDUM AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY US.

THIS MEMORANDUM DOES NOT CONSTITUTE AN OFFER TO SELL OR SOLICITATION OF AN OFFER TO BUY ANY SECURITIES OTHER THAN THOSE OFFERED HEREBY, NOR DOES IT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF AN OFFER TO BUY FROM ANY PERSON IN ANY JURISDICTION IN WHICH IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION. NEITHER THE DELIVERY OF THIS MEMORANDUM NOR ANY SALE MADE HEREUNDER SHALL, UNDER ANY CIRCUMSTANCES, CREATE ANY 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 AFFAIRS OF THE COMPANY SINCE SUCH DATE.

THE SECURITIES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER THE SECURITIES ACT AND SUCH LAWS PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. INVESTORS SHOULD BE AWARE THAT THEY WILL BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME.

THIS MEMORANDUM IS SUBJECT TO AMENDMENT AND SUPPLEMENTATION AS APPROPRIATE.

FOR RESIDENTS OF ALL STATES

IN MAKING AN INVESTMENT DECISION, INVESTORS MUST RELY ON THEIR OWN EXAMINATION OF OUR COMPANY AND THE TERMS OF THE OFFERING, INCLUDING THE MERITS AND RISKS INVOLVED. THESE SECURITIES HAVE NOT BEEN RECOMMENDED BY ANY FEDERAL OR STATE SECURITIES COMMISSION OR REGULATORY AUTHORITY. FURTHERMORE, THE FOREGOING AUTHORITIES HAVE NOT CONFIRMED THE ACCURACY OR DETERMINED THE ADEQUACY OF THIS DOCUMENT. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE. THESE SECURITIES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER THE SECURITIES ACT, AND APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. INVESTORS SHOULD BE ABLE TO WITHSTAND A TOTAL LOSS OF THEIR INVESTMENT.

FOR RESIDENTS OF CALIFORNIA

IT IS UNLAWFUL TO CONSUMMATE A SALE OR TRANSFER OF THESE SECURITIES, OR ANY INTEREST THEREIN, OR TO RECEIVE ANY CONSIDERATION THEREFOR, WITHOUT THE PRIOR WRITTEN CONSENT OF THE COMMISSIONER OF CORPORATIONS OF THE STATE OF CALIFORNIA, EXCEPT AS PERMITTED IN THE COMMISSIONER'S RULES.

FOR RESIDENTS OF CONNECTICUT

THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER SECTION 36-485 OF THE CONNECTICUT UNIFORM SECURITIES ACT AND, THEREFORE, CANNOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF TO ANY PERSON OR ENTITY UNLESS SUBSEQUENTLY REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES ACT OF CONNECTICUT, IF SUCH REGISTRATION IS REQUIRED, OR UNLESS AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE.

NOTICE TO FLORIDA RESIDENTS

THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT, OR THE FLORIDA SECURITIES ACT, BY REASON OF SPECIFIC EXEMPTIONS THEREUNDER RELATING TO THE LIMITED AVAILABILITY OF THE OFFERING.

WHEN SALES ARE MADE TO FIVE OR MORE PERSONS IN FLORIDA, ANY SALE IN FLORIDA MADE PURSUANT TO THE FLORIDA SECURITIES AND INVESTOR PROTECTION ACT SECTION 517.061(11) IS VOIDABLE BY THE PURCHASER IN SUCH SALE EITHER WITHIN 3 DAYS AFTER THE FIRST TENDER OF CONSIDERATION IS MADE BY SUCH PURCHASER TO THE ISSUER OR AN AGENT OF THE ISSUER WITHIN 3 DAYS AFTER THE AVAILABILITY OF THAT PRIVILEGE IS COMMUNICATED TO SUCH PURCHASER, WHICHEVER OCCURS LATER.

THE AVAILABILITY OF THE PRIVILEGE TO VOID SALES PURSUANT TO SECTION 517.061(11) IS HEREBY COMMUNICATED TO EACH FLORIDA OFFEREE. EACH PERSON IS ENTITLED TO EXERCISE THE PRIVILEGE TO VOID SALES GRANTED BY SECTION 517.061(11)(A)(5) AND ANY PERSON WHO WISHES TO EXERCISE SUCH RIGHT MUST, WITHIN THREE DAYS AFTER THE TENDER OF THE PURCHASE PRICE TO THE ISSUER OR AN AGENT OF THE ISSUER (INCLUDING ANY DEALER ON BEHALF OF THE COMPANY OR ANY SALES PERSON OF SUCH DEALER), CAUSE A WRITTEN NOTICE OR TELEGRAM TO BE SENT TO THE COMPANY AT THE ADDRESS PROVIDED IN THE MEMORANDUM—SUCH LETTER OR TELEGRAM MUST BE SENT AND, IF POSTMARKED, POSTMARKED ON OR PRIOR TO THE END OF THE AFOREMENTIONED THIRD DAY. IF A PERSON IS SENDING A LETTER IT IS PRUDENT TO SEND SUCH LETTER BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED, TO ASSURE THAT IT IS RECEIVED AND ALSO TO EVIDENCE THE DATE IT WAS MAILED. PERSONS WHO MAKE THIS REQUEST ORALLY MUST ASK FOR WRITTEN CONFIRMATION THAT THIS REQUEST HAS BEEN RECEIVED.

FOR RESIDENTS OF MASSACHUSETTS

EACH NON-ACCREDITED MASSACHUSETTS PURCHASER OF THESE SECURITIES MUST HAVE A NET WORTH (EXCLUSIVE OF HOME, FURNISHINGS THEREIN AND AUTOMOBILES) EQUAL TO AT LEAST THREE (3) TIMES SUCH INVESTOR'S INVESTMENT HEREIN.

FOR RESIDENTS OF NEW JERSEY

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE BUREAU OF SECURITIES OF THE STATE OF NEW JERSEY, NOR HAS THE BUREAU PASSED ON OR ENDORSED THE MERITS OF THIS OFFERING. THIS OFFERING HAS NOT BEEN FILED WITH THE BUREAU OF SECURITIES. ANY REPRESENTATION TO THE CONTRARY IS UNLAWFUL.

FOR RESIDENTS OF NEW YORK

THIS MEMORANDUM HAS NOT BEEN REVIEWED BY THE ATTORNEY GENERAL OF THE STATE OF NEW YORK PRIOR TO ITS ISSUANCE AND USE. THE ATTORNEY GENERAL OF THE STATE OF NEW YORK HAS NOT PASSED ON OR ENDORSED THE MERITS OF THIS OFFERING. ANY REPRESENTATION TO THE CONTRARY IS UNLAWFUL. THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT, OR THE NEW YORK FRAUDULENT PRACTICES ("MARTIN") ACT, BY REASON OF SPECIFIC EXEMPTIONS THEREUNDER RELATING TO LIMITED AVAILABILITY OF THE OFFERING. THESE SECURITIES CANNOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF TO ANY PERSON OR ENTITY UNLESS SUBSEQUENTLY REGISTERED UNDER THE SECURITIES ACT, OR THE MARTIN ACT, IF SUCH REGISTRATION IS REQUIRED.

FOR RESIDENTS OF OHIO

THE INTERESTS ARE OFFERED PURSUANT TO AN EXEMPTION FROM REGISTRATION UNDER SECTION I707.03 (Q) OF THE OHIO SECURITIES ACT AND MAY NOT BE REOFFERED FOR SALE, TRANSFERRED OR RESOLD IN THE STATE OF OHIO EXCEPT IN COMPLIANCE WITH SUCH ACT AND APPLICABLE RULES PROMULGATED THEREUNDER.

FOR RESIDENTS OF PENNSYLVANIA

UNDER PROVISIONS OF THE PENNSYLVANIA SECURITIES ACT OF 1972, EACH PENNSYLVANIA RESIDENT SHALL HAVE THE RIGHT TO WITHDRAW HIS ACCEPTANCE WITHOUT INCURRING ANY LIABILITY, TO THE SELLER, UNDERWRITER (IF ANY) OR ANY PERSONS, WITHIN TWO (2) BUSINESS DAYS FROM THE DATE OF RECEIPT BY THE ISSUER OF HIS WRITTEN BINDING CONTRACT OF PURCHASE OR IN THE CASE OF A TRANSACTION IN WHICH THERE IS NOT WRITTEN BINDING CONTRACT OF PURCHASE, WITHIN (2) BUSINESS DAYS AFTER HE MAKES THE INITIAL PAYMENT FOR THE SECURITIES BEING OFFERED.

EACH PENNSYLVANIA RESIDENT WHO SUBSCRIBES FOR THE SECURITIES BEING OFFERED HEREBY AGREES NOT TO SELL THESE SECURITIES FOR A PERIOD OF TWELVE MONTHS AFTER THE DATE OF PURCHASE.

TO WITHDRAW A SUBSCRIPTION TO PURCHASE SECURITIES, A SUBSCRIBER NEED ONLY SEND A LETTER OR TELEGRAM TO THE COMPANY AT THE ADDRESS SET FORTH IN THE TEXT OF THIS MEMORANDUM, INDICATING HIS OR HER INTENTION TO WITHDRAW. SUCH LETTER OR TELEGRAM SHOULD BE SENT AND POSTMARKED PRIOR TO THE END OF THE AFOREMENTIONED SECOND BUSINESS DAY. IT IS PRUDENT TO SEND SUCH LETTER BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED, TO ENSURE THAT IT IS RECEIVED AND ALSO TO EVIDENCE THE TIME WHEN IT WAS MAILED. IF THE REQUEST IS MADE ORALLY (IN PERSON OR BY THE TELEPHONE TO THE COMPANY AT THE NUMBER LISTED IN THE TEXT OF THIS MEMORANDUM), A WRITTEN CONFIRMATION THAT THE REQUEST HAS BEEN RECEIVED SHOULD BE REQUESTED.

FOR RESIDENTS OF TEXAS

THESE SECURITIES HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE TEXAS SECURITIES ACT, BY REASON OF SPECIFIC EXEMPTIONS THEREUNDER RELATING TO THE LIMITED AVAILABILITY OF THE OFFERING. THESE SECURITIES CANNOT BE SOLD, TRANSFERRED OR OTHERWISE DISPOSED OF TO ANY PERSON OR ENTITY UNLESS SUBSEQUENTLY REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE TEXAS SECURITIES ACT, IF SUCH REGISTRATION IS REQUIRED, OR UNLESS AN EXEMPTION FROM SUCH REGISTRATION IS AVAILABLE.

FOR RESIDENTS OF ALL OTHER STATES

IF YOU DO NOT LIVE IN ONE OF THE LISTED STATES, THE COMPANY MUST CONFIRM THAT YOUR STATE'S SECURITIES LAWS PERMIT US TO SELL THE SECURITIES TO YOU. ACCORDINGLY, PRIOR TO OBTAINING CLEARANCE IN YOUR STATE OF RESIDENCE, PLEASE DO NOT ATTEMPT TO SUBSCRIBE.

NASAA UNIFORM LEGEND

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. THESE SECURITIES HAVE NOT BEEN RECOMMENDED BY ANY FEDERAL OR STATE SECURITIES COMMISSION OR REGULATORY AUTHORITY. FURTHERMORE, THE FOREGOING AUTHORITIES HAVE NOT CONFIRMED THE ACCURACY OR DETERMINED THE ADEQUACY OF THIS DOCUMENT. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE. THESE SECURITIES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND THE APPLICABLE STATE SECURITIES LAWS, PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. INVESTORS SHOULD BE AWARE THAT THEY WILL BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS MEMORANDUM. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

NOTICE TO FOREIGN INVESTORS

IF YOU LIVE OUTSIDE THE UNITED STATES, IT IS YOUR RESPONSIBILITY TO FULLY OBSERVE THE LAWS OF ANY RELEVANT TERRITORY OR JURISDICTION OUTSIDE THE UNITED STATES IN CONNECTION WITH ANY PURCHASE, INCLUDING OBTAINING REQUIRED GOVERNMENTAL OR OTHER CONSENTS OR OBSERVING ANY OTHER REQUIRED LEGAL OR OTHER FORMALITIES.

SUMMARY

This summary highlights information contained elsewhere in this memorandum and does not contain all of the information that you should consider in making your investment decision. Before investing in our Common Stock, you should carefully read this entire memorandum, including our financial statements and the related notes and the information set forth under the headings "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in each case included elsewhere in this memorandum.

Unless the context otherwise requires, references to the "Company," "we," "our," "us," or "Squarex" in this memorandum mean Squarex Pharmaceutical Corporation, a Delaware corporation.

Our Company

We are a late-clinical-stage pharmaceutical company developing a drug that is intended to improve immune function to reduce severity and incidence of infectious disease with an initial focus on oral herpes (also known as herpes labialis and cold sores. The terms oral herpes, herpes labialis, and cold sores are used interchangeably and with the same meaning throughout this memorandum).

Our drug, SQX770, has completed Phase 1 and Phase 2 placebo-controlled clinical trials and showed a statistically significant[1] effect in non-primary endpoints in both trials of delaying time to next herpes labialis (cold sore) outbreak (from day 1 to day 121 in the Phase 1 and from days 42 to 121 in the Phase 2) and reducing the number of outbreaks of cold sores in the period from 42 to 121 days after a single dose in persons with frequent outbreaks (in the Phase 2) compared to placebo. These were not the planned primary endpoints in either clinical trial and the results failed to meet the planned primary endpoints in each trial. In a third exploratory clinical trial testing the mechanism of action of the drug without a defined primary endpoint, SQX770 was shown to alter the immune response against the herpes simplex virus of patients with frequent outbreaks to more closely match the immune response at the cellular level of persons who are infected with HSV-1 but have few or no oral herpes outbreaks. For instance, eight weeks after one dose of SQX770, expression of interferon gamma, a key antiviral cytokine, by immune cells exposed to herpes simplex virus type 1 (HSV-1) in vitro was significantly increased. The same clinical trial showed that persons infected with HSV-1 with 0 to 2 outbreaks in the prior 12 months had significantly higher interferon gamma expression in the same test than persons with 6 or more outbreaks in the prior 12 months. The drug has been well tolerated in clinical trials with no serious adverse events. None of the data obtained in clinical trials to date would be accepted by the FDA as indicative of efficacy. The FDA will base any approval on the results of Phase 3 clinical trials, which have not been initiated.

The SQX770 drug is topically applied on a patient's arm, not the face or lip or a lesion. In the Phase 3 trials and commercially, we plan to dose patients once every three months.

The use of SQX770 was co-invented by the Company's founder and Chief Executive Officer, Dr. Hugh McTavish.

Our Competitive Strengths

We believe that we possess a number of competitive strengths that position us to become a leading pharmaceutical company focused on oral and genital herpes, including:

- Patent protection with patent exclusivity in the U.S. under method of treatment patents until at least 2036 with a composition of matter patent expiring in 2028.
- Our SQX770 drug has shown a statistically significant effect of preventing oral herpes outbreaks in two of two clinical trials where outbreaks were counted, although the measurement showing significant efficacy (a significant difference between the treatment group and a placebo group) was not the measurement pre-specified as the primary endpoint in either case. SQX770 significantly altered the anti-herpes immune response of immune cells isolated from patients in a third clinical trial, where the alteration eight weeks after one dose of the drug made the immune characteristics of the patients with frequent outbreaks more similar to those of persons infected with HSV-1 but having few or no outbreaks.
- We have completed an End-of-Phase-2 Meeting with the U.S. Food and Drug Administration ("FDA").
- Oral herpes is a common condition, with about 15% of the U.S. and world populations having at least one outbreak each year.
- SQX770 would be the first drug approved for the indication of preventing oral herpes outbreaks.
- SQX770 is relatively inexpensive to manufacture.

Our Business Strategy

Our goal is to be the leader in preventing and treating both oral and genital herpes outbreaks and, potentially, develop drugs for other infectious diseases. Key elements of our strategy include:

- To obtain FDA approval of SQX770 for preventing herpes labialis outbreaks. We believe this to be a potentially enormous market.
- To obtain FDA approval for preventing genital herpes outbreaks. Clinical trials for that indication may be conducted in parallel with the trials for oral herpes. We believe that the genital herpes market potential is probably about the same size as the oral herpes market potential.
- To explore possible uses of SQX770 in other infectious diseases.
- To pursue commercial opportunities for SQX770 in the United States and internationally through out-licensing or partnering with a larger pharmaceutical company.

[1] Throughout this memorandum, the term "significant" when referring to clinical trial data describes the result of comparing measurements of one group to another, usually a treatment group compared to a placebo group, where the groups differ and the P value for the difference is less than 0.05. The P value is a statistical measurement indicating how likely it is that a difference between two groups could have arisen by chance. A P value of less than 0.01 means less than a 1% possibility that the difference arose by chance. Conventionally in statistics, $P<0.05$ is termed a "significant" difference and $P<0.01$ a "highly significant" difference. This memorandum follows that convention.

Recent Developments

Phase 2 shows SQX770 reduces cold sore outbreaks

We have completed a placebo-controlled multi-center Phase 2 clinical trial in 139 patients with 4 or more oral herpes outbreaks per year. SQX770 reduced the number of outbreaks by 2.6-fold in the period from 42 to 120 days after a single topical dose on the arm, compared to placebo ($P<0.01$, highly significant). The primary endpoint was the number of days until the subject reported first new herpes labialis episode following sensitization dose (day 1). This endpoint was not met. The number of days until the subject reported first new herpes labialis beginning from 21 days after the intensification dose (from day 42) was a secondary endpoint, and this endpoint was met.

End-of-Phase-2 Meeting with U.S. FDA

We completed an End-of-Phase-2 meeting with the FDA in which the agency agreed on a clear and achievable path for the remaining clinical trials and toxicology testing before we can file an NDA with the FDA for marketing approval of SQX770 that includes:

- two new toxicology studies in nonhuman animals;
- a bridging Phase 2 clinical trial in about 120 patients testing two dose levels in our planned commercial product of a dermal patch to deliver the drug solution; and
- two Phase 3 clinical trials, each with about 900 patients.

Our Team

We have assembled a highly experienced management team, board of directors (the "Board of Directors") and scientific advisory board to pursue innovative approaches to solving the problems of urgent and unmet medical needs. Squarex is led by an accomplished team with a deep legacy in multiple therapeutic areas and drug development.

Our Founder, Chairman and Chief Executive Officer, Dr. Hugh McTavish, is a biochemist and patent attorney and successful entrepreneur, focusing on advancing innovations in pharmaceuticals.

Our co-founder, Dr. Thomas D. Horn, is a leading dermatologist, former Executive Director of the American Board of Dermatology, and current adjunct professor at Harvard Medical School.

Dr. Arkadiusz Dudek, one of our board members, is a practicing oncologist at the Mayo Clinic and Professor of Medicine at the University of Minnesota. He is the founder and Chief Medical Officer of TTC Oncology, a company developing a novel breast cancer treatment.

Dr. Michael Myers, one of our board members, is Chairman and Chief Executive Officer of Quoin Pharmaceuticals Ltd., an Israeli Nasdaq traded clinical stage, emerging specialty pharmaceutical company, with headquarters in the US, focused on rare skin and orphan diseases for which there are no approved treatments or cures.

Dr. Mark Schwartz, one of our board members, serves as an advisor to several early-stage biotechnology companies and is a faculty member at San Jose State University with appointments in the Masters in Biotechnology Program, the Lucas School of Management in the Business College, and the department of Biology.

Wayne Danson, one of our board members, is a former partner in multiple Big 4 public accounting firms and accomplished C level executive, has over 35 years of experience in international and corporate taxation, financial advisory services including investment banking, and mergers and acquisitions, business strategy, and entrepreneurship.

Constantine Kardaras, Chief Financial Officer, is a CPA with over 35 years of Finance and Accounting experience, including prior experience in the biotechnology and pharmaceutical industries at three companies. He is an alumnus of Deloitte and holds an MBA in Finance from New York University's Stern School of Business.

Implication of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (2) the last day of the fiscal year in which we have total annual gross revenues of at least $1.07 billion, (3) the date on which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of our most recently completed second fiscal quarter or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we may reduce our executive compensation disclosure;
- we may present only two years of audited financial statements, plus unaudited condensed financial statements for any interim period, and related Management's Discussion and Analysis of Financial Condition and Results of Operations in this Memorandum;
- we may avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and
- we may not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

We have availed ourselves in this Memorandum of the reduced reporting requirements described above. As a result, the information that we provide stockholders may be less comprehensive than what you might receive from other public companies. When we are no longer deemed to be an emerging growth company, we will not be entitled to the exemptions provided in the JOBS Act discussed above.

Smaller Reporting Company

We are also currently a "smaller reporting company," meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company, and have a public float of less than $250 million or annual revenues of less than $100 million during the most recently completed fiscal year. In the event that we are still considered a "smaller reporting company," at such time as we cease being an "emerging growth company," the disclosure we will be required to provide in our SEC filings will increase, but will still be less than it would be if we were not considered either an "emerging growth company" or a "smaller reporting company." Specifically, similar to "emerging growth companies," "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as an "emerging growth company" or "smaller reporting company" may make it harder for investors to analyze our results of operations and financial prospects.

Summary of Risks Associated with Our Business

Our business and an investment in our company is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this summary. Some of these risks include:

- We are a pre-revenue company with a limited operating history Since inception, we have incurred significant operating losses. At December 31, 2022, we had an accumulated deficit of approximately $8,256,192;

- We will need substantial additional funding to finance our operations through regulatory approval of one or more of our product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts;

- We depend entirely on the success of our drug product candidate. If we are unable to obtain regulatory approval or commercialize this experimental treatment, or experience significant delays in doing so, our business will be materially harmed;

- We may not be able to successfully develop or commercialize our existing drug product candidate or develop new drug product candidates on a timely or cost-effective basis;

- We depend on one drug product candidate and our business could be materially adversely affected if our key drug product candidate does not perform as well as expected and does not receive regulatory approval;

- We may be in the future, a party to legal proceedings that could result in adverse outcomes;

- Our competitors and other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in resulting litigation, and any unfavorable outcome of such litigation could have a material adverse effect on our business;

- We may experience failures of or delays in clinical trials which could jeopardize or delay our ability to obtain regulatory approval and commence product commercialization;

- We face intense competition from both brand and generic companies who have significant financial resources which could limit our growth and adversely affect our financial results;

- Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could cause significant liability for us and harm our reputation;

- We will be competing against large existing well-funded pharmaceutical companies with existing and proposed competing products;

- We are subject to extensive governmental regulation and we face significant uncertainties and potentially significant costs associated with our efforts to comply with applicable regulations;

- We may not be able to develop or maintain our sales capabilities or effectively market or sell our products;

- Manufacturing or quality control problems may damage our reputation, require costly remedial activities or otherwise negatively impact our business;

- Our profitability may depend on coverage and reimbursement by third-party payors including government agencies, and healthcare reform and other future legislation may lead to reductions in coverage or reimbursement levels;

- We face risks related to health epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our preclinical studies and clinical trials, research activities and therefore our receipt of necessary regulatory approvals could be delayed or prevented;

- We may in the future need to, license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms;

- We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop, manufacture and market our products and product candidates;

- If we fail to comply with our obligations under any of our third-party agreements, we could lose license rights that are necessary to develop our product candidates;

- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel; and

- After this offering, our directors, executive officers and certain stockholders will continue to own a majority of our common stock and, if they choose to act together, will be able to exert absolute control over matters subject to stockholder approval.

Summary of the Offering

Shares being Offered:	Up to 5,000,000 shares at an offering price of $3.00 per share.
Common Stock Outstanding Before this Offering	7,354,502
Common Stock Outstanding After this Offering	12,354,502 shares
Use of Proceeds	Assuming the sale of all shares offered hereby, we expect to receive net proceeds, after deducting commissions to eligible brokers an estimated expenses payable by us, of approximately $13.5 million. We intend to use substantially all of the net proceeds from this offering to continue to fund research and development of SQX770, payment of accrued salaries, repayment of indebtedness to a related party and for working capital and other general corporate purposes. See "Use of Proceeds"
Risk Factors	See "Risk Factors" beginning on page 8 of this memorandum and the other information included in this memorandum for a discussion of factors you should carefully consider before investing in our securities.
Exemption from Registration; Offering Terms	The shares will be sold under an exemption from registration pursuant to Rule 506(c) under the Securities Act of 1933, as amended (the "Securities Act"). No minimum amount of shares is required to be sold in this offering. There may be multiple closings and any proceeds received will be used immediately by the Company.
Investor Status	The shares will be sold exclusively to investors who are accredited as defined in Rule 501 promulgated under the Securities Act. Accredited status must be verified by the Company by one of the methods allowed by applicable law.

The number of shares of our common stock to be outstanding after this offering (i) is based on 7,354,502 shares of our common stock outstanding as of May 31, 2023, (ii) does not include 111,937 shares of common stock issuable upon the automatic conversion of outstanding SAFEs, or Simple Agreement for Future Equity Interests, on the date of the completion of this offering and (iii)) does not include 23,810 shares of common stock issuable upon the automatic conversion of two convertible promissory notes in the aggregate principal amount of $50,000.

RISK FACTORS

Any investment in our Common Stock involves a high degree of risk. Investors should carefully consider the risks described below and all of the information contained in this memorandum before deciding whether to purchase our Common Stock. Our business, financial condition and results of operations could be materially adversely affected by these risks if any of them actually occur. This memorandum also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this memorandum.

Risks Related to Our Financial Position and Need for Additional Capital

We are a late clinical stage pharmaceutical company with a limited operating history.

We were established and began operations in 2012. Our operations to date have been limited to financing and staffing our company and conducting Phase 1 and Phase 2 clinical trials of our SQX770 formulation to reduce outbreaks of oral herpes. We have not yet demonstrated the ability to successfully obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early clinical stage pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to, among other things:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound;
- successfully manufacture our clinical product candidates and establish a commercial supply;
- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of our product candidates;
- secure market exclusivity and/or adequate intellectual property protection for our product candidates;
- attract and retain an experienced management and advisory team;
- secure acceptance of our product candidates in the medical community and with third-party payors and consumers;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan; and
- utilize the funds that we do have and/or raise in this offering or in the future to efficiently execute our business strategy.

If we cannot successfully execute any one of the foregoing, our business may fail and your investment will be adversely affected.

We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability.

We are a late clinical stage pharmaceutical company with a limited operating history and have incurred losses since our formation. We incurred net losses of approximately $556,437 and approximately $364,179 for the years ended December 31, 2022, and 2021, respectively. We have not commercialized any product candidates and have never generated revenue from the commercialization of any product. To date, we have devoted most of our financial resources to research and development, including clinical development, and to intellectual property.

We expect to incur significant additional operating losses for the next several years, at least, as we advance SQX770 through clinical development, complete clinical trials, seek regulatory approval and commercialize our formula, if approved. The costs of advancing product candidates into each clinical phase tend to increase substantially over the duration of the clinical development process. Therefore, the total costs to advance any of our product candidates to marketing approval in even a single jurisdiction will be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of any products or achieve or maintain profitability. Our expenses will also increase substantially if and as we:

- are required by the FDA, to complete the various phases in human trials;
- establish a sales, marketing and distribution infrastructure to commercialize our drug, if approved, and for any other product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific and commercial personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our transition to a public reporting company; and
- acquire or in-license or invent other product candidates or technologies.

Furthermore, our ability to successfully develop, commercialize and license any product candidates and generate product revenue is subject to substantial additional risks and uncertainties, as described under "Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval" and "Risks Related to Commercialization." As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize one or more product candidates, either alone or through collaborations, or if revenues from any product that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the value of our common stock will be materially and adversely affected.

Even if this offering is successful, we will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our drugs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to advance the clinical development of and launch and commercialize our product candidates if we receive regulatory approval. Following this offering, we will require additional capital for further research and development and next phase clinical trials of SQX770 may also need to raise additional funds sooner to pursue a more accelerated development of our drug product. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs, clinical trials or any future commercialization efforts.

We believe that the net proceeds from this offering will enable us to fund our operating expense requirements through 12 months if $7 million is raised following the closing of this offering. We have based this estimate on assumptions that may prove to be wrong, and we could deploy our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the:

- progress, timing, costs and results of clinical trials, including patient enrollment in such trials, for SQX770 or any other future product candidates;
- various clinical development plans we establish for SQX770 and any other future product candidates;
- number and characteristics of product candidates that we discover or in-license and develop, if any;
- outcome, timing and cost of regulatory review by the FDA and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we planned for;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effects of competing technological and market developments;
- costs and timing of the implementation of commercial-scale manufacturing activities;
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval; and
- cost associated with being a public company.

If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be, in hindsight, favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

There is substantial doubt about our ability to continue as a going concern.

Our independent public accounting firm in its report dated March 28, 2023, included an explanatory paragraph expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Going concern contemplates the realization of assets and the satisfaction of liabilities in the normal course of business over a reasonable length of time. Our ability to continue as a going concern ultimately is dependent on our ability to generate a profit which is dependent upon our ability to obtain additional equity or debt financing, attain further operating efficiencies and, ultimately, to achieve profitable operations. As a result, our financial statements do not reflect any adjustment which would result from our failure to continue to operate as a going concern. Any such adjustment, if necessary, would materially affect the value of our assets.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

Clinical trials are expensive, time-consuming and difficult to design and implement, and involve an uncertain outcome.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Because the results of early clinical trials are not necessarily predictive of future results, SQX770 may not have favorable results in future preclinical and clinical studies or receive regulatory approval. We may experience delays in initiating and completing any clinical trials that we intend to conduct, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence a trial;
- reaching an agreement on acceptable terms with prospective contract research organizations (“CROs”), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board (“IRB”), approval at each site, or Independent Ethics Committee (“IEC”), approval at sites outside the United States;
- recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers;
- having patients complete a trial or return for post-treatment follow-up;

- imposition of a clinical hold by regulatory authorities, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements or follow trial protocols;

- clinical sites deviating from trial protocol or dropping out of a trial;

- addressing patient safety concerns that arise during the course of a trial;

- adding a sufficient number of clinical trial sites; or

- manufacturing sufficient quantities of product candidate for use in clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board ("DSMB") for such trial or the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including clinical trial data collection, and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in "Risks Related to Our Dependence on Third Parties".

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for SQX770 or any other product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain regulatory approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for SQX770 or any other product candidate. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval of a New Drug Application ("NDA") from the FDA. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates, or other products containing the active ingredient in our product candidates;

- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;

- the FDA or comparable foreign authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;

- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- the FDA or comparable foreign regulatory authorities may disagree with our safety interpretation of our product candidate;

- the FDA or comparable foreign regulatory authorities may disagree with our efficacy interpretation of our product candidate; and

- the FDA or comparable foreign regulatory authorities may regard our CMC package as inadequate.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market SQX770 or another product candidate, which would significantly harm our business, results of operations and prospects.

In addition, the FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in

enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the nature of the trial protocol;
- the existing body of safety and efficacy data with respect to the product candidate;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions;
- our ability to maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

We face risks related to health epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our preclinical studies and clinical trials, and therefore our receipt of necessary regulatory approvals could be delayed or prevented.

We face risks related to health epidemics or outbreaks of communicable diseases. For example, the recent outbreak around the world, including in the United States, the European Union (the "EU") members, China and many other countries, of the highly transmissible and pathogenic COVID-19 and its Omicron variant. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries, which in the case of COVID-19 has occurred. In addition, the COVID-19 pandemic and its resulting lockdowns, and travel and other similar restrictions are having a severe effect on the clinical trials of many drug candidates. Some trials have been merely delayed, while others have been cancelled. The extent to which the COVID-19 pandemic may impact our clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and geographic reach of the outbreak, the severity of COVID-19, and the effectiveness of actions to contain and treat COVID-19. The continued spread of COVID-19 globally could adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Disruptions or restrictions on our ability to travel to monitor data from our clinical trials, or to conduct clinical trials, or the ability of patients enrolled in our studies to travel, or the ability of staff at study sites to travel, as well as temporary closures of our facilities or the facilities of our clinical trial partners and their contract manufacturers, would negatively impact our clinical trial activities. In addition, we rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials,

including the collection of data from our clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our preclinical trials could be delayed and/or disrupted by the COVID-19 pandemic. As a result, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our financial results.

Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.

The results of preclinical studies, early clinical trials or analyses of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our clinical trials for SQX770 are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval.

Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Our product candidates may cause serious adverse events or undesirable side effects, which may delay or prevent marketing approval, or, if approved, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Serious adverse events or undesirable side effects caused by our products could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Any clinical trials for our drug product candidates to date may fail to demonstrate acceptable levels of safety and efficacy which could prevent or significantly delay their regulatory approval or result in a more restrictive label by the FDA or other comparable foreign authorities.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or the IRBs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial

or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to implement a Risk Evaluation and Mitigation Strategy ("REMS") or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

The market opportunities for our products, if approved, may be smaller than we anticipate.

We expect to initially seek approval for SQX770. Our estimate of market potential for the SQX770 formulation has been derived from a variety of sources, including scientific literature, patient foundations, and market research, and may prove to be incorrect. Even if we obtain significant market share for any product candidate, if approved, if the potential target populations are smaller than we anticipate, we may never achieve profitability without obtaining marketing approval for additional indications.

We have never obtained marketing approval for our product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approval would prevent us from commercializing our product candidate, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidate, which could significantly harm our business.

Even if we obtain FDA approval for our product candidate in the United States, we may never obtain approval for or commercialize our product candidate in any other jurisdiction, which would limit our ability to realize their full market potential.

To market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for our product candidates, we will still face extensive and ongoing regulatory requirements and obligations and any product candidates, if approved, may face future development and regulatory difficulties.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice ("cGMP") requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and Good Clinical Practice ("GCP") requirements for any clinical trials that we conduct post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If any of our product candidates receive marketing approval, the accompanying label may limit the approved indicated use of the product candidate, which could limit sales of the product candidate. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the FDCA relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Further, the FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Potential product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

The use of SQX770 or any other product candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;

- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize SQX770 or any other product candidate;
- product recalls, withdrawals, or labeling, marketing, or promotional restrictions;
- decreased market demand for any product; and
- loss of revenue.

Risks Related to Commercialization

We face significant competition from other pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The pharmaceutical industry is highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to acquire, develop, and obtain marketing approval for new products on a cost-effective basis and to market them successfully. We face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies in the United States and other jurisdictions. These organizations may have significantly greater resources than we do and may conduct similar research; seek patent protection; and establish collaborative arrangements for research, development, manufacturing and marketing of products that may compete with us.

Our competitors may, among other things:

- have significantly greater name recognition, financial, manufacturing, marketing, drug development, technical, and human resources than we do, and future mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors;
- develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe effects;
- obtain quicker regulatory approval;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel; establishing clinical trial sites and patient registration; and in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, or are more convenient or are less expensive than SQX770. Our competitors may also obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for SQX770, which could result in our competitors establishing or strengthening their market position before we are able to enter the market.

The successful commercialization of SQX770 and any other product candidate we develop will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels, and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as SQX770, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our drug and any other product candidates we develop. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar, or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and offer to reimburse patients only for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

We may also be subject to extensive governmental price controls and other market regulations outside of the United States, and we believe the increasing emphasis on cost-containment initiatives in other countries have and will continue to put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits.

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our

product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

Even if SQX770 or any product candidate we develop receives marketing approval, it may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success.

If SQX770 or any product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. If it does not achieve an adequate level of acceptance, we may not generate significant product revenues or become profitable. The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product together with other medications.

Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

If we are unable to establish sales, marketing, and distribution capabilities either on our own or in collaboration with third parties, we may not be successful in commercializing SQX770, if approved.

We do not have any infrastructure for the sales, marketing, or distribution of SQX770, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market and successfully commercialize our drug or any product candidate we develop, if approved, we must build our sales, distribution, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these

services. Although we plan to license to or partner with a larger pharmaceutical company to market SQX770 if approved, we may choose to or need to build a focused sales, distribution and marketing infrastructure to market SQX770, if approved, in the United States and Europe. There are significant expenses and risks involved with establishing our own sales, marketing and distribution capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of that product. For example, if the commercial launch of SQX770 for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe our products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our product candidates, if approved, in certain markets overseas. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in a product and such collaborator's ability to successfully market and sell the product. We intend to pursue collaborative arrangements regarding the sale and marketing of SQX770, if approved, for certain markets overseas; however, we cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we are unable to build our own sales force or negotiate a collaborative relationship for the commercialization of SQX770, we may be forced to delay the potential commercialization of the drug or reduce the scope of our sales or marketing activities. If we need to increase our expenditures to fund commercialization activities for SQX770 we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. We may also have to enter into collaborative arrangements for SQX770 at an earlier stage than otherwise would be ideal and we may be required to relinquish rights to it or otherwise agree to terms unfavorable to us. Any of these occurrences may have an adverse effect on our business, operating results, and prospects.

If we are unable to establish adequate sales, marketing, and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates and may never become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

A variety of risks associated with operating internationally could materially adversely affect our business.

We currently have no international operations, but our business strategy includes potentially expanding internationally if any of our product candidates receive regulatory approval. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;

- additional potentially relevant third-party patent rights;

- complexities and difficulties in obtaining protection and enforcing our intellectual property;

- difficulties in staffing and managing foreign operations;

- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;

- limits in our ability to penetrate international markets;

- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;

- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;

- certain expenses including, among others, expenses for travel, translation and insurance; and

- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm any future international expansion and operations and, consequently, our results of operations.

Risks Related to Our Dependence on Third Parties

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Our employees and independent contractors, including principal investigators, CROs, consultants, vendors and any third parties we may engage in connection with development and commercialization of our product candidates, could engage in misconduct, including intentional, reckless or negligent conduct or unauthorized activities that violate: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse and other healthcare laws and regulations; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation.

It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We currently rely on third-party contract manufacturing organizations ("CMOs") for the production of clinical supplies of SQX770 and intend to rely on CMOs for the production of commercial supplies of SQX770, if approved. Our dependence on CMOs may impair or delay the development and commercialization of the drug, which would adversely impact our business and financial position.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials and commercial quantities of SQX770 and any product candidates we develop, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. We intend to have manufactured a sufficient clinical supply of SQX770 drug substance to enable us to complete our clinical trials, and we intend to engage a CMO to provide clinical and commercial supplies of the drug products.

The facilities used to manufacture our product candidates must be inspected by the FDA and comparable foreign authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be essentially dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacture of our product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers the raw materials necessary to produce our product candidates. We do not and will not have control over the process or timing of the acquisition of these raw materials by our CMOs. Supplies of raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption

of the manufacture of our product candidates. Although we generally have not begun and do not intend to begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

We intend to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We rely, and will continue to rely, on CROs, CRO-contracted vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards.

We and our CROs will be required to comply with the Good Laboratory Practice ("GLP") requirements for our preclinical studies and GCP requirements for our clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs fail to comply with these requirements, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with any CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects. In addition:

- the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers; and

- the loss of, or a disruption in our relationship with, any one or more collaborators could harm our business.

If any collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed, and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this memorandum also apply to the activities of any collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all.

In addition, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of our product candidates. If a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business and our stock price could be adversely affected.

We may in the future collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely affected.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

Current and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set.

In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the

Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the "ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted, or injected;

- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs thereby potentially increasing a manufacturer's Medicaid rebate liability;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;

- expansion of the entities eligible for discounts under the Public Health Service program; and

- a licensure framework for follow-on biologic products.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011, resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the orphan drug tax credit was reduced as part of a broader tax reform. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand;

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act (the "
which, among other things, impose criminal and civil penalties, including through civil whistleblower or q
actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S.
government, claims for payment or approval that are false or fraudulent, knowingly making, using or causin
made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making
statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In additi
government may assert that a claim including items and services resulting from a violation of the U.S. federa
Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. A claim includes "any req
demand" for money or property presented to the federal government. In addition, manufacturers can be held
under the FCA even when they do not submit claims directly to government payors if they are deemed to "
the submission of false or fraudulent claims;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, which impose, among other things, specified requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the U.S. federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state 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 preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our consulting agreements and other relationships with physicians and other healthcare providers, some of whom might receive stock or stock options as compensation for their services, could be subject to challenge under one or more of such laws. Ensuring that our current and future internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Any clinical trial programs we conduct or research collaborations we enter into in the European Economic Area may subject us to the General Data Protection Regulation.

If we conduct clinical trial programs or enter into research collaborations in the European Economic Area, we may be subject to the General Data Protection regulation ("GDPR"). The GDPR applies extraterritorially and implements stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals, a comprehensive individual data rights regime, data export restrictions governing transfers of data from the European Union (the "EU") to other jurisdictions, short timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data, other special categories of personal data and coded data and additional obligations if we contract third-party processors in connection with the processing of personal data. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

We are subject to environmental, health and safety laws and regulations, and we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities.

Our operations, including our development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, the production efforts of our third-party manufacturers or our development efforts may be interrupted or delayed.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology, products, and product candidates or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our drug development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to SQX770 and any future products and product candidates. We currently hold four U.S. patents as well as patents issued in foreign countries.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our patent rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. However, in certain instances, the laws of the United States are more restrictive than those of foreign countries. For example, a recent series of Supreme Court Cases has narrowed the types of subject matter considered eligible for patenting.

Accordingly, certain diagnostic methods are considered ineligible for patenting in the U.S. because they are directed to a "law of nature". Further, publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology, products, or product candidates, in whole or in part, or patents being issued which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated, held unenforceable, in whole or in part, or reduced patent term. Such a result could limit our ability to stop others from using or commercializing similar or identical technologies and products to ours. Moreover, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. While various extensions may be available, the life of a patent is limited. Without patent protection for our current or future products, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from using or commercializing technologies or products similar or identical to ours.

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We may become subject to third parties' claims alleging infringement of their patents and proprietary rights, or we may need to become involved in lawsuits to protect or enforce our patents, which could be costly, time consuming, delay or prevent the development and commercialization of our products and product candidates or put our patents and other proprietary rights at risk.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our products and product candidates without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. Litigation relating to infringement or misappropriation of patent and other intellectual property rights in the pharmaceutical and biotechnology industries is common, including patent infringement lawsuits, interferences, oppositions, reexamination, derivation and post-grant proceedings before the U.S. Patent and Trademark Office ("USPTO"), and corresponding foreign patent offices. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Numerous U.S., European and other foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products and product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We may be subject to third-party claims including infringement, interference or derivation proceedings, post-grant review and inter parties review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. These proceedings may also result in our patent claims being invalidated, held unenforceable or narrowed in scope. Similarly, if our patents or patent applications are challenged during interference or derivation proceedings, a court may hold that a third-party is entitled to certain patent ownership rights instead of us. Further, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, methods of manufacture, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable products and product candidates unless we obtained a license or until such patents expire or are finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. If we are found to have infringed such rights willfully, the damages may be enhanced and may include attorneys' fees. Further, if a patent infringement suit is brought against us or our third-party service providers, our development, manufacturing or sales activities relating to the product or product candidate that is the subject of the suit may be delayed or terminated. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require us to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if a license can be obtained on acceptable terms, the rights may be nonexclusive, which could give our competitors access to the same intellectual property rights. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our products and product candidates, forced to modify such products and product candidates, or to cease some aspect of our business operations, which could harm our business significantly. Modifying our products and product candidates to design around third-party intellectual property rights may result in significant cost or delay to us and could prove to be technically infeasible. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products and product candidates.

If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products and product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of eligibility, lack of written description, lack of novelty, obviousness or non-enablement. Third parties might allege unenforceability of our patents because someone connected with prosecution of the patent withheld relevant information, or made a misleading statement, during patent prosecution. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity of patents, for example, we cannot be certain that there is no invalidating prior art of which we or the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products and product candidates. Furthermore, our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors view these announcements in a negative light, the price of common stock could be adversely affected.

Finally, even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop, manufacture and market our products and product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our products and product candidates in any jurisdiction. For example, in the United States, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States, Europe and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our future products and product candidates, or their manufacture or use may currently be unpublished. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products and product candidates or the use thereof. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and product candidates. We may incorrectly determine that our products and product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States, Europe or elsewhere that we consider relevant

may be incorrect, which may negatively impact our ability to develop and market our products and product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates.

From time to time we may identify patents or applications in the same general area as our products and product candidates. We may determine these third-party patents are irrelevant to our business based on various factors including our interpretation of the scope of the patent claims and our interpretation of when those patents expire. If the patents are asserted against us, however, a court may disagree with our determinations. Further, while we may determine that the scope of claims that will issue from a patent application does not present a risk, it is difficult to accurately predict the scope of claims that will issue from a patent application, our determination may be incorrect, and the issuing patent may be asserted against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our products and product candidates. We might, if possible, also be forced to redesign our products and product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products and product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical and pharmaceutical industries involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical and pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, which was passed in September 2011, resulted in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent before the USPTO. This applies to all of our U.S. patents, even those effectively filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the enforcement or defense of our owned and in-licensed patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in

the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, European Patent Office ("EPO") and other foreign patent offices over the lifetime of a patent. In addition, the USPTO, EPO and other foreign patent office's require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such noncompliance will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our products and product candidates or if we or our licensors otherwise allow our owned or licensed patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our products and product candidates in any indication for which they are approved.

We enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents covering our products and product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our owned and in-licensed technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States or the Europe. These products may compete with our products and product candidates, and our owned or in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our owned and in-licensed patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for and launch generic versions of our products. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk

of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for our products, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from using or commercializing technologies or products similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, we may be able to extend the term of a patent covering each product candidate under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent that is applicable to and covers an approved drug may be extended. Similar provisions are available in Europe, such as supplementary protection certificates, and in certain other non-United States jurisdictions to extend the term of a patent that covers an approved drug. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of a patent term extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

Further, under certain circumstances, the term of a patent covering our products may be extended for time spent during the pendency of the corresponding patent application in the USPTO (referred to as Patent Term Adjustment, or PTA). The laws and regulations underlying how the USPTO calculates the PTA is subject to change and any such PTA granted by the USPTO could be challenged by a third-party. If we do not prevail under such a challenge, the PTA may be reduced or eliminated, resulting in a shorter patent term, which may negatively impact our ability to exclude competitors.

Because PTA added to the term of patents covering pharmaceutical products has particular value, our business may be adversely affected if the PTA is successfully challenged by a third party and our ability to exclude competitors is reduced or eliminated.

Intellectual property rights do not address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to SQX770 or our future products or product candidates but that are not covered by the claims of the patents that we own or license from others;
- others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights;
- we or any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or any of our collaborators might not have been the first to file patent applications covering certain technologies we or they own or have obtained a license, or will own or obtain a license;
- issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- ownership and inventorship of our patents or patent applications may be challenged by third parties; and
- patents of third parties, or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. Because we expect to rely on third parties to manufacture SQX770 and any future products and product candidates, and we expect to collaborate with third parties on the development

of SQX770 and any future products and product candidates, we must, at times, share trade secrets with them. We also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. However, trade secrets or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, collaborators, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, collaborators, contractors and advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of our employees, consultants, collaborators, contractors and advisors to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary for the development or commercialization of SQX770 or our future products or product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize SQX770 or our products or product

candidates, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, which could materially harm our business. At this time, we are unaware of any intellectual property that interferes with ours or is complementary and needed to commercialize SQX770.

We may be subject to claims that our employees, consultants, collaborators, contractors or advisors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, consultants, collaborators, contractors, advisors and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants, collaborators, contractors and advisors have inadvertently or otherwise used or disclosed confidential information of their former employers or other third parties. We may also be subject to claims that the former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Our proprietary information may be lost, or we may suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

Risks Related to Our Employees, Managing Our Growth and Our Operations

Our future success depends on our ability to retain our key personnel and to attract, retain and motivate qualified personnel.

We are, and will in the future be, highly dependent on the development, regulatory, commercialization and business development expertise of our senior management team, as well as the other principal members of our scientific and clinical teams. Although we have employment agreements, offer letters or consulting agreements with our executive officers, these agreements do not prevent them from terminating their services at any time.

If we lose one or more of our executive officers or key employees, our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop product candidates, gain regulatory approval, and commercialize new products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and

advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be engaged by entities other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize product candidates will be limited.

We expect to expand our development, regulatory, and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, sales and marketing and financial and systems operations. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities or acquire new facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may not strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and nondisruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Our business and operations would suffer in the event of system failures.

Our computer systems, as well as those of our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access including ransomware attacks, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of SQX770 or any other product candidate could be delayed.

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

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 confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security

breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we will take steps to protect such information and invested in information technology, there can be no assurance 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 of 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 reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. 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 or cash flow.

Risks Related to this Offering and Our Common Stock

Following this offering, our directors, executive officers and certain stockholders will continue to own a significant percentage of our common stock and, if they choose to act together, will be able to exert significant control over matters subject to stockholder approval.

Upon the closing of this offering, our Chairman and Chief Executive Officer, and other members of our executive management will beneficially own approximately 32% to 53% of the voting power of our outstanding common stock. As a result, they will likely have control over the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. These individuals also have significant control over our business, policies and affairs as officers and directors of our company. Therefore, you should not invest in reliance on your ability to have any control over our company.

Our shares are not publicly traded. If and when we become a publicly traded company, because we are a pharmaceutical startup and a smaller reporting company, the market price of our common stock will likely be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our shares are not publicly traded. If and when we become a publicly traded company, because we are a startup with a limited track record, the market price of our common stock will likely be highly volatile. The market price of our common stock may be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in the commencement, enrollment and ultimate completion of our clinical trials;
- any delay in submitting an NDA and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- failure to successfully develop and commercialize SQX770 or any future product candidate;
- inability to obtain additional funding, particularly given the current banking crisis;

- regulatory or legal developments in the United States and other countries applicable to SQX770 or any other product candidate;
- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of companies similar to ours;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic collaborations, joint ventures, or capital commitments by us or our competitors;
- significant lawsuits, including patent or stockholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- general economic, industry and market conditions;
- health epidemics and outbreaks, including the COVID-19 pandemic, which could significantly disrupt our preclinical studies and clinical trials, and therefore our receipt of necessary regulatory approvals could be delayed or prevented; and
- the other factors described in this "Risk Factors" section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These price fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political, regulatory and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance. In particular, stock markets have experienced extreme volatility in 2020 and 2021 due to the ongoing COVID-19 pandemic, among other factors, and investor concerns and uncertainty related to the impact of the pandemic on the economies of countries worldwide. The recent bank industry crisis has also negatively impacted the stock price volatility for companies in the pharmaceutical industry, as a number of pharmaceutical companies relied on Silicon Valley Bank for their commercial banking needs.

Furthermore, the market has seen instances, particularly with companies that have smaller public float, where there have been extreme run-ups and rapid declines in the company's stock price following their initial public offering. As a small start-up company in the pharmaceutical industry, our stock price may be very volatile following our initial public offering, including the possibility for rapid run ups and/or rapid declines in the stock price that are not directly related to our operating performance and financial condition. This could make it difficult for prospective investors to evaluate the current value of our Company's stock. The market price of our common stock may decline below the public offering price, and you may lose some or all of your investment.

Our management has broad discretion in using the net proceeds from this offering.

We have stated, in only a general manner, how we intend to use the net proceeds from this offering. See "Use of Proceeds." We cannot, with any assurance, be more specific at this time. We will have broad discretion in the timing of the expenditures and application of proceeds received in this offering. If we fail to apply the net proceeds effectively, we may not be successful in bringing our proposed products to market. You will not have the opportunity to evaluate all of the economic, financial or other information upon which we may base our decisions to use the net proceeds from this offering.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future. See "Dividend Policy" for additional information.

If you purchase shares of our common stock in this offering, you will incur immediate dilution in the book value of your shares.

The public offering price of our common stock will be substantially higher than the as adjusted net tangible book value per share of our common stock. Therefore, if you purchase our common stock in this offering, you will pay a price per share of our common stock that substantially exceeds the book value of our net tangible assets after subtracting our liabilities. Further, the future exercise of any outstanding options and/or warrants to purchase shares of our common stock will cause you to experience additional dilution. See "Dilution."

Anti-takeover provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our certificate of incorporation, bylaws and Delaware law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our Board of Directors. Our corporate governance documents include provisions:

- authorizing "blank check" preferred stock, which could be issued by our Board of Directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;

- limiting the liability of, and providing indemnification to, our directors and officers;

- controlling the procedures for the conduct and scheduling of Board of Directors and stockholder meetings; and

- providing our Board of Directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which generally prevents stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This memorandum, including the sections entitled "Summary," "Risk Factors," "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business," contains forward-looking statements. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements concerning the following:

- our lack of operating history;
- fluctuations in the trading price of our common stock;
- the expectation that we will incur significant operating losses for the foreseeable future and will need significant additional capital following this offering;
- our current and future capital requirements to support our development and commercialization efforts for our product candidates and our ability to satisfy our capital needs;
- our dependence on one product candidate, which is still in early stage of clinical development;
- our, or that of our third-party manufacturers, ability to manufacture cGMP quantities of our product candidates as required for pre-clinical and clinical trials and, subsequently, our ability to manufacture commercial quantities of our product candidates;
- our ability to complete required clinical trials for our product candidates and obtain approval from the FDA or other regulatory agencies in different jurisdictions;
- our lack of a sales and marketing organization and our ability to commercialize our product candidates if we obtain regulatory approval;
- our dependence on third-parties to manufacture our product candidates;
- our reliance on third-party CROs to conduct our clinical trials;
- our ability to maintain or protect the validity of our intellectual property;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements;
- our ability to adequately support organizational and business growth; and
- the continued spread of COVID-19 and the resulting global pandemic and its impact on our preclinical studies and clinical studies.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this memorandum. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this memorandum may not occur and actual results could differ materially and adversely from those anticipated or implied in our forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this memorandum to conform these statements to actual results or to changes in our expectations, except as required by law.

USE OF PROCEEDS

We estimate that the net proceeds we will receive from the sale of our common stock in this offering, after deducting commissions payable to eligible broker dealers and estimated expenses payable by us, will be approximately $13.5 million.

We currently expect to use the net proceeds from this offering for product development activities, including clinical and regulatory research and development for our product candidates and future clinical trials. Approximately $400 thousand will be used to pay accrued salaries payable to our executives and employees. In addition, approximately $650 thousand will be used to repay indebtedness owed to our Chief Executive Officer under a $1.0 million line of credit entered into on October 1, 2019. Amounts outstanding under the line of credit from time to time accrue interest at the rate of 15% per annum. Under the line of credit agreement, we are obligated to repay an amount equal to 10% of the first $1.0 million in investment funds raised, 20% of the second $1.0 million raised, and 100% of amounts above $2.0 million until the debt is repaid in full. The entire amount must be repaid by December 31, 2024.

In addition to the amounts set forth above, we currently expect to use the net proceeds from this offering to be used for the following purposes:

- Approximately $3.6 million for Phase 2 clinical trial;
- Approximately $0.5 million for drug manufacturing and testing; and

the remainder for working capital and general corporate purposes including the associated costs of operating as a public company.

Based on our current projections, we believe that $7 million of net proceeds from this offering will fund our operations for at least 12 months from the date of this memorandum.

We may also use a portion of the net proceeds of this offering for the acquisition or licensing, as the case may be, of additional technologies, other assets or businesses, or for other strategic investments or opportunities, although we currently have no understandings, agreements or commitments to do so.

Although we currently anticipate that we will use the net proceeds from this offering as described above, there may be circumstances where a reallocation of funds is necessary. The amounts and timing of our actual expenditures will depend upon numerous factors, including the results of our pre-clinical studies and planned clinical trials, our sales and marketing and commercialization efforts, demand for our products, our operating costs and the other factors described under "Risk Factors" in this memorandum. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

The net proceeds from this offering, together with our cash and marketable securities, are not expected to be sufficient for us to fund our product candidate through regulatory approval, and we may need to raise additional capital to complete the development and commercialization of our product candidate. We estimate that the total amount needed to obtain regulatory approval and bring our product candidate to market may be $70 million. Accordingly, following the completion of this offering, we will need to raise additional funds through public offerings and/or private placement of our equity or debt securities.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Investors should not purchase our common stock with the expectation of receiving cash dividends. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our Board of Directors deems relevant, and subject to the restrictions contained in any future financing instruments.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion summarizes the significant factors affecting the operating results, financial condition, liquidity and cash flows of our company as of and for the periods presented below. The following discussion and analysis should be read in conjunction with "Summary—Summary Financial Information," "Selected Financial Information" and the financial statements and the related notes thereto included elsewhere in this memorandum. The statements in this discussion regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and all other non-historical statements in this discussion are forward-looking statements and are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including those discussed below and elsewhere in this memorandum, particularly in the section entitled "Risk Factors." This discussion and analysis are based upon the historical financial statements of Squarex Pharmaceutical Corporation included in this memorandum. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31.

Overview

We are a pharmaceutical company developing a late-clinical-stage drug intended to improve immune function to reduce severity and incidence of infectious disease. The first indication for the drug is *preventing* outbreaks of herpes labialis—cold sores or oral herpes. We are developing a drug formulation code named SQX770 that contains the active ingredient squaric acid dibutyl ester (SADBE). We have completed three clinical trials for oral herpes. SQX770 had statistically significant effects in delaying or reducing the number of oral herpes outbreaks in patients with frequent outbreaks in two of the trials and caused statistically significant changes in measurements of immune characteristics in ways that correlated with persons with fewer oral herpes outbreaks. None of those significant results were in the pre-specified primary endpoints of the clinical trials. None of the data obtained in clinical trials to date would be accepted by the FDA as indicative of efficacy. The FDA will base any drug approval of SQX770 and conclusions of efficacy on the results of Phase 3 clinical trials, which have not been initiated.

We have an open Investigational New Drug Application (IND) with the FDA, IND number 118615, that allows us to conduct all of our clinical trials of SQX770 for the indication of prevention of herpes labialis outbreaks.

We have also completed an End-of-Phase-2 meeting with the FDA with agreement on the remaining clinical trials and non-clinical work to be done prior to filing a New Drug Application with the FDA for marketing approval for the indication of preventing herpes labialis outbreaks.

Squarex was formed in June 2012 as a Delaware limited liability company. To date, we have raised a total of approximately $6.5 million in debt and equity financing and used those funds to complete pre-clinical development, a Phase 1, a Phase 2, and a Phase 1 mechanism of action clinical trial in oral herpes and complete an End-of-Phase 2 meeting with the FDA.

We expect to resume clinical trials in mid-2023 with a Phase 2 bridging clinical trial and begin the pivotal Phase 3 trials in early 2024. Patients will be followed in the Phase 3 trials for 12 months.

We have incurred significant operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future. We have no products approved for commercial sale and have never generated any revenues from product sales. Through December 31, 2020, we have raised net cash proceeds of approximately $6.0 million to fund operations through equity and debt financings. In 2021, we raised approximately $160 thousand in debt and $54 thousand from the exercise of warrants. In 2022, the Company raised $92 thousand in debt, and $235 thousand from a regulation crowdfunding equity offering. Our net loss was $556,437 and $364,179 for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $8,256,192 and cash, cash equivalents and investments of $5,177. The Company has not generated any revenue to date.

We expect our expenses and operating losses will increase substantially as we conduct our remaining planned clinical trials, continue our research and development activities, initiate commercial preparation activities, and seek regulatory approvals for our product candidates, as well as hire additional personnel, protect our intellectual property and continue to incur additional costs associated with being a public company. In addition, as our product candidates progress through development and toward commercialization, we will need to make milestone payments to the licensor from whom we have in-licensed a portion of the rights to our product candidate. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in particular on the timing of our clinical trials and preclinical studies and our expenditures on other research and development activities.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which could take a number of years. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Accordingly, until such time as we can generate substantial product revenues to support our cost structure, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional capital when needed, we could be forced to delay, limit, reduce or terminate our product candidate development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

License Agreement with BioVentures

The original invention of a treatment that prevents oral herpes outbreaks that was the basis for Squarex was invented jointly by Dr. Hugh McTavish, who assigned his interest to Squarex, and Dr. Thomas D. Horn and Dr. Sandra M. Johnson, who were employees of the University of Arkansas for Medical Sciences. They assigned their rights to BioVentures, LLC, the licensing arm of The Board of Trustees of the University of Arkansas. That invention was the basis for U.S. Patent application no. 12/450,586, and continuations thereof, which are now U.S. Patent Numbers 9,205,065 and 10,744,084, and Korean Patent No. 10-2009-7023035.

Squarex has an exclusive license for the rights belonging to BioVentures, LLC, (the licensing arm of the Board of Trustees of the University of Arkansas) in U.S. Patent application no. 12/450,586, and continuations thereof, which are now U.S. Patent Numbers 9,205,065 and 10,744,084, and a Korean patent no. 10-2009-7023035.

COVID-19 Outbreak

On January 30, 2020, the World Health Organization announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 Outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 Outbreak as a pandemic, based on the rapid increase in exposure globally.

Although to date we have not been directly affected by the pandemic, with the proliferation of new variants of the virus, there is the chance that future shutdowns will have a material adverse impact on the Company's financial condition, liquidity, and future results of operations including our ability to conduct future clinical drug trials. Management is actively monitoring the possible impact of the global pandemic on its financial condition, liquidity, operations, industry, and workforce.

Components of Results of Operations

Operating expenses

Research and development expenses

Our research and development expenses consist primarily of testing and developing costs, materials and supplies, consulting services and other direct expenses. Research and development costs are expensed as incurred.

General and administrative expenses

General and administrative expenses consist primarily of professional fees for legal and accounting services as well as other operating expenses.

Sales and Marketing

Sales and marketing costs are expensed as incurred and relate primarily to costs associated with developing our corporate website, investor relations and presentations, traditional and social media, corporate branding and messaging, and strategic communications and business development plans.

Results of operations for the years ended December 31, 2022 and 2021

The following table sets forth our statements of operations data for the following periods:

			Change	
Years Ended December 31,	***2022***	***2021***	***Dollars***	***Percentage***
Operating Expenses:				
Sales and marketing	$ 9,823	$ 4,150	$ 5,673	137%
Research and development	74,110	71,044	3,066	4%
General and administrative	379,332	232,778	146,554	63%
Total operating expenses	$ 463,265	$ 307,972	$ 155,293	50%
Loss from operations	$ (463,265)	$ (307,972)	$ (155,293)	50%
Other Income (Expense):				
Interest expense, net	$ (4,179)	$ (3,250)	$ (929)	29%
Interest expense- related party, net	(88,993)	(52,957)	(36,036)	68%
Total other income (expense), net	$ (93,172)	$ (56,207)	$ (36,965)	66%
Loss before income tax provision	$ (556,437)	$ (364,179)	$ (192,258)	53%
Income tax provision	$ -	$ -	$ -	0%
Net Loss	**$ (556,437)**	**$ (364,179)**	**$ (192,258)**	**53%**

Components of Results of Operations

Operating expenses

Research and development expenses

Our research and development expenses consist primarily of testing and developing costs, materials and supplies, consulting services and other direct expenses. Research and development costs are expensed as incurred.

General and administrative expenses

General and administrative expenses consist primarily of professional fees for legal and accounting services as well as other operating expenses.

Operating expenses

Research and development expenses

Research and development expenses relate primarily to preclinical and clinical development of our product candidates. Our research and development expenses include or could include:

- salaries and related expenses for personnel, travel expenses, and expenses related to stock-based compensation granted to personnel in development functions;
- external expenses paid to clinical trial sites, contract research organizations and consultants that conduct our clinical trials;
- expenses related to drug formulation development and the production of nonclinical and clinical trial supplies, including fees paid to contract manufacturers;
- licensing milestone payments related to development, regulatory or commercialization events;
- expenses related to nonclinical studies;
- expenses related to compliance with drug development regulatory requirements; and
- other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of equipment, and other supplies.

Research and development expenses of $74,110 in 2022 and $71,044 in 2021 were substantially lower than in prior years because the clinical trials we have conducted were completed in 2019. Research and development expenses are expected to increase substantially after completion of this offering because the proceeds from this offering will allow us to resume our clinical trials.

We expense research and development costs as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue to further our clinical development pipeline. Product candidates in later stages of clinical development, as SQX770 is, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to be significant over the next few years as we increase personnel and compensation costs and further our development

programs and prepare to seek regulatory approval for our product candidates. It is difficult to determine with certainty the duration and completion costs of any clinical trial we may conduct.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel and consultants in executive, finance and other administrative functions. Other significant costs include facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and other services and insurance costs.

We expect that our general and administrative expenses will increase in the future as we expand our operating activities, increase headcount, as well as incur additional costs associated with being a publicly traded company and maintaining compliance with exchange listing and SEC requirements, if and when we become a publicly traded company. These increases will likely include increased personnel expenses, legal fees, accounting fees, directors' and officers' liability insurance premiums and fees associated with investor relations and maintaining compliance with exchange listing and SEC requirements associated with operating as a public company.

We had $379,332 in general and administrative expenses in 2022 compared to $232,778 in 2021. The increase was primarily attributed to an increase in professional services to support increasing corporate compliance and administration.

Sales and Marketing

The Company has only nominal sales and marketing expenses since our lead product is in clinical trials and not FDA approved. We had $9,823 sales and marketing expenses in 2022 and $4,150 in 2021. As we near regulatory approval we may incur significant marketing expenses and expenses associated with hiring a sales force.

Other (income) expenses

Interest expense

Interest expense was $4,179 for the twelve months ended December 31, 2022, and $3,250 for the twelve months ended December 31, 2021. In addition, related party interest expense on our line of credit was $88,993 for the twelve months ended December 31, in 2022 and $52,957 for the twelve months ended December 31, 2021.

Cash Flow Summary for the years ended December 31, 2022 and 2021

The following table shows a summary of our cash flows for each of the periods shown below:

	Years Ended	
	December 31, 2022	**December 31, 2021**
Net cash used in operating activities	$ (340,276)	$ (183,001)
Net cash provided by financing activities	310,152	213,793
Net increase (decrease) in cash	$ (30,124)	$ 30,792

Operating activities

During the year ended December 31, 2022, cash used in operating activities was $340,276, due to a net loss of $556,437 that was partially offset by $204,881 change in operating assets and liabilities, and $11,280 in non-cash stock compensation expense.

During the year ended December 31, 2021, cash used in operating activities was $183,001, due to a net loss of $364,179 that was partially offset by $180,929 change in operating assets and liabilities, and $249 in operating lease related expenses.

Investing activities

During the years ended December 31, 2022, and December 31, 2021, there were no investing activities.

Financing activities

During the year ended December 31, 2022, $310,152 was provided by financing activities due to $235,067 in gross proceeds from the issuance of SAFEs net of $17,630 in issuance costs, $50,000 from the issuance of convertible notes, and $122,865 in drawdowns net of $80,150 in repayments on the line of credit provided by a related party.

During the year ended December 31, 2021, $213,793 was provided by financing activities due to $159,793 in drawdowns on the line of credit provided by a related party and $54,000 provided by the exercise of outstanding warrants.

Liquidity and Capital Resources

We have generated no revenues, have incurred operating losses since inception, and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. We have an accumulated deficit of $8,256,192 as of December 31, 2022, and future losses are anticipated. These factors, among others, raise substantial doubt as to our ability to obtain additional debt or equity financing and our ability to continue as a going concern. Until such time as we are able to establish a revenue stream from the sale of our therapeutic products, we are dependent upon obtaining necessary equity and/or debt financing to continue operations. We cannot make any assurances that sales of our drug products will commence in the near term or that additional financings will be available to us and, if available, on acceptable terms or at all.

There can be no assurance that we will be able to secure the necessary debt or equity financings to continue our drug development and clinical trial plans at all or on terms acceptable to us. This could negatively impact our business and operations and could also lead to the reduction of our business and drug development operations. Consequently, the accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, there are material risks and uncertainties that raise substantial doubt about our ability to continue as a going concern within one year from the date these financial statements are available to be issued. These financial statements do not include any adjustments relating to the recovery of recorded assets or the classification of the liabilities that might be necessary should we be unable to continue as a going concern.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of its financial condition and results of operations is based on its financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis. The most significant estimate relates to the valuation allowance of deferred tax assets resulting from net operating losses. We base our estimates and assumptions on current facts, historical experiences, and various other factors that the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and

results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our audited financial statements, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Research and Development Expenses

Research and development costs include costs incurred for internal and external research and development activities to develop drug candidates and are expensed as incurred in the accompanying statement of operations. Research and development costs consist of personnel costs, external laboratory supplies and facility costs, as well as fees paid to third party entities that conduct certain research and development activities on our behalf.

We record accrued liabilities for incurred cost of research and development activities conducted by service providers, which include activities under agreements with various Contract Research Organizations for preclinical and clinical studies and contract manufacturing activities. We record the costs of research and development activities based upon the number of services provided and include these costs in accrued and other current liabilities in the accompanying balance sheet and within research and development expense in the accompanying interim condensed statement of operations.

Net Loss per Share of Common Stock

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, convertible debt, SAFEs, stock options and restricted stock units are considered to be potentially dilutive securities.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective is not expected to have a material impact on our financial position or results of operations upon adoption.

Adopted

In October 2020, the FASB issued ASU No. 2020-10, Codification Improvements, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The updated guidance is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company adopted ASU 2020-10 as of the reporting period beginning January 1, 2021. The Company has assessed that the adoption of this new standard did not have a material impact on our accompanying financial statements for the reporting periods of 2022 and 2021.

In August 2020, the FASB issued ASU No. 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)-Accounting For Convertible Instruments and Contracts in an Entity's Own Equity. The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU also simplifies the diluted net income per share calculation in certain areas. The new guidance is effective for annual and interim periods beginning after December 15, 2021, and early adoption is permitted for fiscal years beginning after December 15, 2020, and interim

periods within those fiscal years. We have adopted ASU No. 2019-12 as of the reporting period beginning January 1, 2022 with such adoption having no material impact on the Company's financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740) : Simplifying the Accounting for Income Taxes. This guidance is intended to improve consistent application and simplify the accounting for income taxes. This ASU removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance. This standard is effective for annual reporting periods beginning after December 15, 2020, including interim reporting periods within those annual reporting periods, with early adoption permitted. We have adopted ASU No. 2019-12 as of the reporting period beginning January 1, 2021 with such adoption having no material impact on the Company's financial statements.

CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Effective December 8, 2022, our auditors, L&L CPAS, PA (the "Former Accountant"), resigned as our independent certified public accountant due to its decision to cease all audit assignments on behalf of public companies.

The Former Accountant's report on the financial statements for the fiscal year ended December 31, 2021 was not subject to an adverse or qualified opinion or a disclaimer of opinion and was not modified as to uncertainty, audit scope or accounting principles for the fiscal years then ended, except that the Former Accountant's report on the financial statements as of December 31, 2021 contained explanatory language that substantial doubt existed about the Company's ability to continue as a going concern due to an accumulated deficit, recurring losses, and the expectation of continuing future losses.

During the two most recent fiscal years and the subsequent interim period through the date of the resignation of the Former Accountant, there were no reportable events as the term is described in Item 304(a)(1)(v) of Regulation S-K.

During the two most recent fiscal years and the subsequent interim period through the date of resignation of the Former Accountant, there were no disagreements with the Former Accountant on any matters of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which, if not resolved to the satisfaction of the Former Accountant would have caused it to make reference to the subject matter of the disagreements in connection with its reports on these financial statements for those periods.

We engaged M&K CPAS, PLLC, as our new independent certified public accountant, effective January 23, 2023.

BUSINESS

Summary

We are a pharmaceutical company developing a late-clinical-stage drug that is intended to improve immune function to reduce severity and incidence of infectious disease. The first indication for the drug is preventing outbreaks of herpes labialis—cold sores or oral herpes. The drug formulation we are developing is code named SQX770 and contains the active ingredient squaric acid dibutyl ester (SADBE). We have completed three clinical trials of SQX770 for the prevention of oral herpes.

We have also completed an End-of-Phase-2 meeting with the U.S. FDA with agreement on the remaining clinical trials and non-clinical work to obtain NDA approval for the indication of preventing herpes labialis outbreaks.

We have an open Investigational New Drug Application (IND) with the FDA, IND number 118615, that allows us to conduct all of our clinical trials of SQX770 for the indication of prevention of herpes labialis outbreaks.

We have completed three clinical trials and our development plans are to conduct the following clinical trials in order to obtain FDA approval:

- A Phase 2 bridging clinical trial in which we will test a dermal patch for delivering the drug formulation. The dermal patch will be part of a kit we plan for use in the commercial product. The Phase 2 bridging clinical trial will be placebo-controlled and involve recruiting 120 patients. We will administer doses on day one and at three months and follow the patients to six months.

- Two multi-center placebo-controlled Phase 3 trials conducted in parallel. Each will involve recruiting approximately 900 patients, dosing them at day one and at three, six and nine months. We will follow the patients for 12 months from day one. The Phase 3 trials will use our planned commercial product, which we expect will include the dermal patch as the delivery device.

We plan to complete the bridging Phase 2 trial approximately 9 to 12 months after this offering, and plan to begin the Phase 3 trials approximately 12 to 15 months after this offering.

Recent Developments

Phase 2 shows SQX770 reduces cold sore outbreaks

We have completed a placebo-controlled multi-center Phase 2 clinical trial in 139 patients with 4 or more oral herpes outbreaks per year. SQX770 cut number of outbreaks by 2.6-fold in the period from 42 to 120 days after a single topical dose on the arm compared to placebo ($P<0.01$, highly significant).[1] SQX770 failed to meet the planned primary endpoint in this trial of extending time to next outbreak from day 1 after the topical dose to the arm. (It extended time to next outbreak from day 1 but the result was not statistically significant.)

Successful End-of-Phase-2 Meeting with U.S. FDA

We completed an End-of-Phase-2 meeting with the FDA in which the agency agreed on a clear and achievable path for the remaining clinical trials and toxicology testing before we can file an NDA with the FDA for marketing approval of SQX770 that would include only:

- two new toxicology studies in nonhuman animals;
- a bridging Phase 2 clinical trial in about 120 patients testing two dose levels in our planned commercial product of a dermal patch to deliver the drug solution; and
- two Phase 3 clinical trials, each with about 900 patients (600 on drug and 300 on placebo).

[1] The results of the clinical trial were published here: Chang ALS, Honari G, Guan L, Zhao L, Palli MA, Horn TD, Dudek AZ, McTavish H. A phase 2, multi-center, placebo-controlled study of single dose squaric acid dibutyl ester (SADBE) to reduce frequency of outbreaks in subjects with recurrent herpes labialis. *Journal of the American Academy of Dermatology* 2020 Dec;83(6):1807-1809.

Herpes labialis is a common condition characterized by blisters or erosions on the lips and skin around the mouth and nose[2] [3] [4]. Most cases are caused by herpes simplex virus type 1 (HSV-1), but 10-15% of cases are caused by HSV-2 with this percentage reportedly increasing[3]. In a population survey in the U.S., 76% of adults were positive for IgG antibodies against HSV-1[5]. A population survey of over 10,000 randomly selected adults in France found 15.1% had a herpes labialis episode in the previous 12 months, and of those with herpes labialis 14.2% had 6 or more occurrences in the last 12 months[6], which is 2.1% of the entire population[7].

Thus, in the U.S. with a population of 330 million, we estimate that 15% of the population, or 50 million individuals, have an oral herpes outbreak in a given year and seven million persons have six or more outbreaks each year.

The natural history of HSV-1 infection leading to herpes labialis is that typically HSV-1 initially infects oral mucosa, and then migrates to sensory neurons and establishes latency, typically in the trigeminal ganglion. The virus is later activated from latency by various events including fever, stress, cold or flu infection, immunosuppression, and sunlight. Upon activation, the virus migrates down sensory neurons to epithelial cells, typically on the vermillion border of the lip, and causes keratinocyte cell lysis and outbreaks as epidermal lesions[8]. Outbreaks usually last one to two weeks. The frequency and severity of outbreaks is thought to be dependent on the effectiveness of immune control of the virus[9] [10].

In the U.S., 11.9% of persons ages 14 to 49 have HSV-2 infection. There are an estimated 572,000 new genital herpes infections per year[11].

Our Solution

We apply SQX770, a solution of squaric acid dibutyl ester (SADBE) in a dimethylsulfoxide (DMSO) carrier, to a penny-sized spot on the arm once every three months. It will be applied by a dermal patch, similar to a BAND-AID or nicotine patch, applied to the inner aspect of the upper arm. To date in our clinical trials SQX770 has been applied with a cotton swab to a spot on the inner aspect of the upper arm and the spot was then covered by TEGADERM. We plan that the commercial product and the product in our Phase 3 clinical trials will be the dermal patch and the Phase 2 bridging clinical trial will test the dermal patch.

SQX770 appears to act by altering the immune response to the herpes virus. Our clinical trial study of the mechanism of action of SQX770 found that a single dose to the arm of patients two months later caused a shift of the immune response from what is called a Type 2 immune response to a Type 1 response and from an antibody response to a T cell response. It caused significantly greater expression of interferon gamma in white blood cells that were stimulated by contact with herpes virus and caused significantly decreased expression of interleukin-5. Interferon gamma is a key antiviral immune modulator. Both of those changes—high interferon gamma and low interleukin-5 expression—are also characteristic of people who are infected with HSV-1 but have few or no outbreaks: in other words, those who have good immune control of the virus.

[2] Woo, S. B., and S. J. Challacombe. 2007. Management of recurrent oral herpes simplex infections. *Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod.* 103 Suppl:S12.e11-18.
[3] Sarnoff, D. S. 2014. Treatment of recurrent herpes labialis. J. Drugs Dermatol. 13:1016-1018.
[4] Opstelten, W., A. K. Neven, and J. Eekhof. 2008. Treatment and prevention of herpes labialis. *Can. Fam. Physician* 54:1683-1687.
[5] Parks, C.G., M. E. Andrew, L. A. Blanciforti, and M. I. Luster MI. 2007. Variation in the WBC differential count and other factors associated with reporting of herpes labialis: a population-based study of adults. *FEMS Immunol. Med. Microbiol.* 51:336-343.
[6] Lorette, G., A. Crochard, V. Mimaud, P. Wolkenstein, J. F. Stalder, A. El Hasnaoui. 2006. A survey on the prevalence of orofacial herpes in France: the INSTANT Study. J. Am. Acad. Dermatol. 55:225-232.
[7] Stalder, J.F. et al. Prevalence and Quality of Life of Patients Suffering from Herpes Labialis with in France – Instant Study. *Value in Health* 2013. Vol. 6, No. 6, p. 760. These are the best data we are aware of for the incidence of herpes labialis episodes, as opposed to HSV-1 infection. Most other studies, including CDC data, are of seroprevalence of HSV-1 infection, which the U.S. CDC reports is 47.8% of the U.S. population. (McQuillan G. et al. Prevalence of Herpes Simplex Virus Type 1 and Type 2 in Persons Aged 14–49: United States, 2015–2016, NCHS Data Brief No. 304, February 2018). Based on that high prevalence of HSV-1 infection in the U.S. we believe it is not likely that symptomatic illness differs dramatically from that in France.
[8] Nicoll, M.P., J. T. Proenca, and S. Efstathiou. 2012. The molecular basis of herpes simplex virus latency. *FEMS Microbiol. Rev*. 36:684-705.
[9] McKenna, D. B., W. A. Neill, and M. Norval. 2001. Herpes simplex virus-specific immune responses in subjects with frequent and infrequent orofacial recrudescences. *British J. Dermatology* 144:459-464.
[10] Daheshia, M., L. T. Feldman, and B. T. Rouse. 1998. Herpes simplex virus latency and the immune response. Curr. Opin. Microbiol. 1:430-436.
[11] Centers for Disease Control and Prevention, Genital Herpes – CDC Fact Sheet (Detailed)

Summary of clinical trials

Clinical Trial	**Phase 1.** Clinicaltrials.gov identifier NCT01971385	**Phase 2.** ClinicalTrials.gov Identifier: NCT02965781	**Phase 1 Mechanism of Action.** ClinicalTrials.gov Identifier: NCT03661541
Design	Placebo-controlled, 28 patients on SQX770, 15 on Placebo	Placebo-controlled, 92 patients on SQX770, 37 on Placebo	12 patients with 6 or more outbreaks per year, white blood cells collected and tested for response to HSV-1 virus in vitro prior to one dose of SQX770 and again 8 weeks after the dose. 24 comparator persons infected with HSV-1 having 0 to 2 outbreaks per year.
Endpoints	Time to next outbreak	Primary endpoint: days to next outbreak after a single dose on day 1. Secondary endpoint: Number of outbreaks over days 42-121 after a single dose.	(There were no planned primary endpoints. All the endpoints were exploratory.) Expression of immune genes in white blood cells stimulated with HSV-1 in treated patients with 6 or more outbreaks and comparison group infected with HSV-1 but having only 0-2 outbreaks per year.

Result Highlights	Median time to next outbreak 40 days in placebo group vs. more than 122 days in SQX770 group, p<0.01, highly significant.	Primary endpoint: Median time to next outbreak from day 1 in placebo group 84 days versus in SQX770 group 107 days. Difference not significant (p=0.9) Secondary endpoints over days 42-121: ● 2.6-fold fewer outbreaks in SQX770 group than placebo (P<0.01). ● 2.4-fold longer time to next outbreak (P<0.05), and ● significantly less severe outbreaks (P<0.05).	Altered immune response to herpes virus in patients with 6 or more outbreaks per year and made it more like that in persons infected HSV-1 but with few or no outbreaks. Significantly increased leukocyte interferon gamma expression, significantly decreased interleukin-5 expression, shifted immune response from type 2 antibody response to more effective type 1 cellular response. Significantly increased leukocyte proliferation against HSV-1.
Publication	McTavish H, Kimball A, Horn TD. Immunotherapy of recurrent herpes labialis with squaric acid. *JAMA Dermatology* 2017;153:828-829.	Chang ALS, Honari G, Guan L, Zhao L, Palli MA, Horn TD, Dudek AZ, McTavish H. A phase 2, multi-center, placebo-controlled study of single dose squaric acid dibutyl ester (SADBE) to reduce frequency of outbreaks in subjects with recurrent herpes labialis. *Journal of the American Academy of Dermatology* 2020 Dec;83(6):1807-1809.	McTavish H, Zerebiec KW, Zeller JC, Shekels LL, Matson MA, Kren BT. Immune characteristics correlating with HSV-1 immune control and effect of squaric acid dibutyl ester on immune characteristics of subjects with frequent herpes labialis episodes. *Immunity Inflammation and Disease* 2019;7(1):22-40.

Phase 1. Safety and Efficacy of Squaric Acid Dibutyl Ester for Treatment of Herpes Labialis.

Clinicaltrials.gov Identifier: NCT01971385

The Phase 1 clinical trial was conducted at Massachusetts General Hospital in 43 patients who reported six or more herpes labialis episodes in the prior 12 months. Patients were randomized 2:1 to receive on a double-blind basis SQX770 [2% squaric acid dibutylester (SADBE) in dimethylsulfoxide (DMSO)] on the arm on day one and then a lower concentration of SADBE on the lip on the site of a lesion at their next outbreak occurring after day 15 or to receive placebo (DMSO only) on both occasions. The primary endpoints were safety and time to next outbreak after the last treatment dose on a lesion.

Results:

The data was not significant for time to next outbreak after the last treatment dose on a lesion because 16 of 28 patients in the treatment group (receiving SQX770) did not experience an outbreak in the study and thus never received a treatment dose on the lesion. In that way we discovered in this trial that the second dose on the lesion was not necessary. Therefore, we analyzed time to next outbreak after the sensitization dose on the arm.

After a single dose to the arm, the patients receiving the placebo had an outbreak but most getting the drug did not experience an outbreak in the 124-day follow up period. Median time to next outbreak after the single dose on the arm was 40 days in the placebo group vs. greater than 124 days in the drug-treated group, a highly significant difference ($P<0.01$).

The study drug was well tolerated. Adverse events consisted primarily of reversible redness at the drug application site. There were no serious adverse events. In the treatment groups, 13 of 35 patients who enrolled experienced non-serious redness, swelling, or itching at the application site versus 2 of 19 in the placebo group. One subject in the treatment group and one in the placebo group experienced a different non-serious adverse event.

Details of and results of this clinical trial are posted at:
https://clinicaltrials.gov/ct2/show/NCT01971385?term=NCT01971385&draw=2&rank=1

Mechanism of Action Phase 1. Immune Characteristics Correlating With HSV-1 Immune Control and Effect of Squaric Acid Dibutyl Ester on Immune Characteristics of Subjects With Frequent Herpes Labialis Episodes.

ClinicalTrials.gov Identifier: NCT03661541

In this study, three groups of patients were recruited. All patients tested positive for antibodies against HSV-1:

- (A) 12 patients with six or more episodes of cold sores in the prior 12 months
- (B) 12 patients with one or two episodes in the prior 12 months
- (C) 12 patients with no episodes in 12 months

Blood was collected from these persons and white blood cells isolated and tested for proliferation in vitro when stimulated with HSV-1-infected cell extracts and free HSV-1 virus. RNA was also isolated from the peripheral blood mononuclear cells (PBMCs) after incubation in the three stimuli and expression of 41 immune-related genes quantified by quantitative real-time PCR. Also, serum anti-HSV-1 IgG levels were quantified.

After the blood collection on day one, the persons in group A (frequent cold sore sufferers) were treated with a single topical application of SQX770 (2% squaric acid dibutyl ester (SADBE) in DMSO), applied to the inner aspect of the upper arm. These subjects returned on days 15 and 57 for blood collection, and their PBMCs were tested again on those dates for proliferation in vitro against the same stimuli and for gene expression and for serum anti-HSV-1 IgG levels.

This was an exploratory study with no pre-specified primary endpoint.

Results:

PBMC proliferation in vitro to HSV-1 and other stimuli.

PBMC proliferation in response to all three stimuli showed the same trends of group C> B > A. In other words, PBMC from those with better immune control of HSV-1, proliferated more than those with worse immune control. The difference was not statistically significant for any one stimulus, but the response to all three stimuli taken together was significantly greater in group C than group A.

PBMC proliferation against HSV-1 of the group A subjects was significantly greater on day 57 than on day one prior to drug treatment. The PBMC proliferative response to all three stimuli taken together was also significantly greater on day 57 than day one in the group A subjects. Therefore, in terms of proliferative response, the group A subjects were more like the group C subjects with good immune control of HSV infection 56 days after SQX770 treatment than they had been on day 1 before drug treatment.

Figure. Proliferation (±Standard Error of the Mean) of PBMCs collected from frequent cold sore sufferers (Group A), infrequent cold sore sufferers (Group B), and persons with zero cold sores in the prior twelve months (Group C). (CPM is counts per minute.)

		Stimulus					
Group and day		Negative control (media only)	HSV-infected cell extract	HSV-1	Candida	Concanavalin A positive control	All 3 test conditions, normalized as percent of C1 averages
A1	CPM	719 (±137)	13240 (±2621)	7134 (±1431)	4016 (±1145)	83020 (±10486)	
	Relative proliferation		20.36 (±3.65)	10.63 (±1.74)	5.79 (±1.46)	36.78 (±20.27)	38.67% (±4.41%)
A15	CPM	719 (±46)	15206 (±3739)	10086 (±2038)	4533 (±1483)	81524 (±11272)	
	Relative proliferation		19.66 (±4.23)	13.35 (±2.24)	5.8 (±1.79)	111.46 (±11.70)	41.47% (±5.31%)
A57	CPM	701 (±139)	15651 (±2811)	12635 (±2516)	7349 (±2078)	96986 (±11468)	
	Relative proliferation		28.20 (±6.49)	21.92 (±5.53)	11.84 (±2.75)	225.23 (±66.92)	68.70% (±9.49%)
	P-value vs A1		$P = 0.249$	$P = 0.079$	$P = 0.044$	$P = 0.211$	$P = 0.005$
B1	CPM	770 (±62)	16147 (±2956)	10824 (±2279)	4791 (±1204)	93337 (±11452)	
	Relative proliferation		21.84 (±4.42)	14.12 (±2.82)	5.85 (±1.21)	128.56 (±19.69)	44.23% (±5.46%)
C1	CPM	629 (±99)	17036 (±2895)	11344 (±1960)	8588 (±2743)	103421 (±12809)	
	Relative proliferation		42.22 (±15.06)	27.13 (±8.89)	20.25 (±7.86)	241.98 (±55.25)	100.00% (20.09%)
	P-value vs A1		$P = 0.172$	$P = 0.082$	$P = 0.084$	$P = 0.094$	$P = 0.004$

Relative proliferation is CPM in the test stimulus/CPM in negative control (medium only). *P* values are for Relative Proliferation in the test condition versus A1, by paired *t*-test for A57 versus A1 and unpaired *t*-test for C1 versus A1.

Anti-HSV-1 IgG

Groups C and B pooled together had significantly lower anti-HSV-1 IgG levels than group A. Among group A subjects, anti-HSV-1 IgG levels were lower on day 57 than on day one, although not significantly so.

Table. Levels of anti-HSV1 IgG.

Units	Group and day	Group average (n=12)	Group St. Dev.	p value*	Sample minus A1	Sample/A1
IV	A1	8.32	1.90			
IV	A15	9.39	1.59	0.197	1.08	1.13
IV	A57	7.58	1.56	0.158	-0.73	0.91
IV	B1	6.61	1.65	0.028	-1.71	0.79
IV	C1	7.16	1.90	0.151	-1.15	0.86
IV	C1+B1	6.88	1.84	0.038	-1.43	0.83

*p values are from two-tailed unpaired t-test for groups B and C vs. A and from two-tailed paired t-test for days 15 and 57 vs. day 1 in group A. n=12 in each group, except n=24 for the pooled groups C+B.

Immune gene expression

For every immune-related gene where any differences were significant the direction of these changes match:

1. Expression in PBMCs upregulated (or downregulated) by HSV-1 (or other stimulus).
2. Same upregulated gene was more expressed in the presence of HSV-1 (or other stimulus) in group C and B subjects (those with zero or infrequent herpes labialis episodes) than group A subjects (those with frequent herpes labialis episodes). (If the gene was downregulated by the stimulus, then it was also found to be less expressed in groups C and B than group A.)
3. Same upregulated gene was more expressed in the presence of HSV-1 (or other stimulus) in group A subjects on day 57 after treatment with SQX770 than on day one before treatment. (If the gene was downregulated by the stimulus, then it was also found to be less expressed in group A on day 57 than day 1.)

Therefore, in every case where there was significant difference, the SQX770 treatment changed the group A subjects by day 57 to make them much more like the group B and C subjects who have better immune control of their HSV-1 infection than the group A subjects were on day one.

Interferon Gamma (IFNG a Th1 cytokine) was the gene (1) most consistently upregulated by a large amount in all three stimuli versus negative control, (2) most consistently increased by the greatest amount in its expression in groups B+C versus group A on day one in all three stimuli, and (3) most consistently increased in its expression by the greatest amount in group A on day 57 vs. day one in all three stimuli. Interleukin-5 (IL5 a Th2 cytokine) (1) was not upregulated by any of the three stimuli and (2) was less expressed in groups B+C than group A day 1 in both HSV-1 virus and HSV-1-infected cell extracts, and (3) was less expressed in group A on day 57 than day 1 in both HSV-1 virus and HSV-1-infected cell extracts.

The absolute gene expression levels of IFNG and IL5 in the presence of HSV stimulus is shown in the table below.

Gene expression as percentage of Group A day 1

Group (Number of outbreaks)	Day	IFNG	IL5	IFNG/IL5 ratio
A. 6+	1	100	100	100
B. 1 or 2	1	355	50*	757**
C. 0	1	302*	63*	515**
A. 6+	56	1,106**	56*	2,528**

*significant (P<0.05) vs. Group A day 1
**highly significant (P<0.01) vs. Group A day 1

A single dose of SQX770 applied to the persons with 6 or more outbreaks per year caused an 11-fold increase in interferon gamma expression and a 25-fold increase in the interferon-gamma to interleukin-5 ratio. Those numbers are not only a highly significant improvement but made the subjects significantly better in those measurements than the subjects who had few or no cold sore outbreaks.

The data indicate that cell-mediated immunity is more important than humoral immunity and a type 1 cell-mediated response more important than a type-2 response in control of HSV-1 infection and indicate that PBMC proliferation in vitro in response to the HSV-1 virus correlates with effective immune control. Interferon gamma (IFNG) was possibly found to be the gene whose expression in PBMCs is most correlated with effective immune control of HSV-1 and whose expression in PBMCs in the presence of HSV-1 virus was also significantly increased by SQX770 treatment of patients.

Adverse events:

Twelve subjects were treated once with SQX770 on the arm. No serious adverse events occurred. One reported nausea. Two reported a mild temporary skin reaction at the site of application involving redness or itching.

Conclusion:

In patients with six or more outbreaks in the prior 12 months, a single topical dose of 2% SQX770 applied to the arm on day 1 significantly improved immune response to HSV-1 by eight weeks later as compared to day zero in the same patients before the application of SQX770, especially in increasing interferon gamma expression and decreasing interleukin-5 expression, both of which correlated with fewer cold sore outbreaks.

Details and results of this clinical trial are published at:
https://clinicaltrials.gov/ct2/show/NCT03661541?term=NCT03661541&draw=2&rank=1

Phase 2. A PHASE 2, MULTI-CENTER, PLACEBO-CONTROLLED STUDY OF SQUARIC ACID DIBUTYL ESTER (SADBE) TREATMENT IN SUBJECTS WITH RECURRENT HERPES LABIALIS: ONE DOSE OF SADBE REDUCES FREQUENCY OF OUTBREAKS

ClinicalTrials.gov Identifier: NCT02965781

Background: Herpes labialis is a common condition that causes painful blisters or sores around lips for which a proven remedy affecting the natural history of the infection has not been yet found. We have previously demonstrated in our Phase 1 clinical trial that SQX770 [2% squaric acid dibutyl ester (SADBE) in DMSO] can delay outbreaks of herpes infection compared to placebo. The present study was performed to determine if a topical application of SADBE to the upper arm could prevent herpes labialis reactivation or reduce the severity of outbreaks.

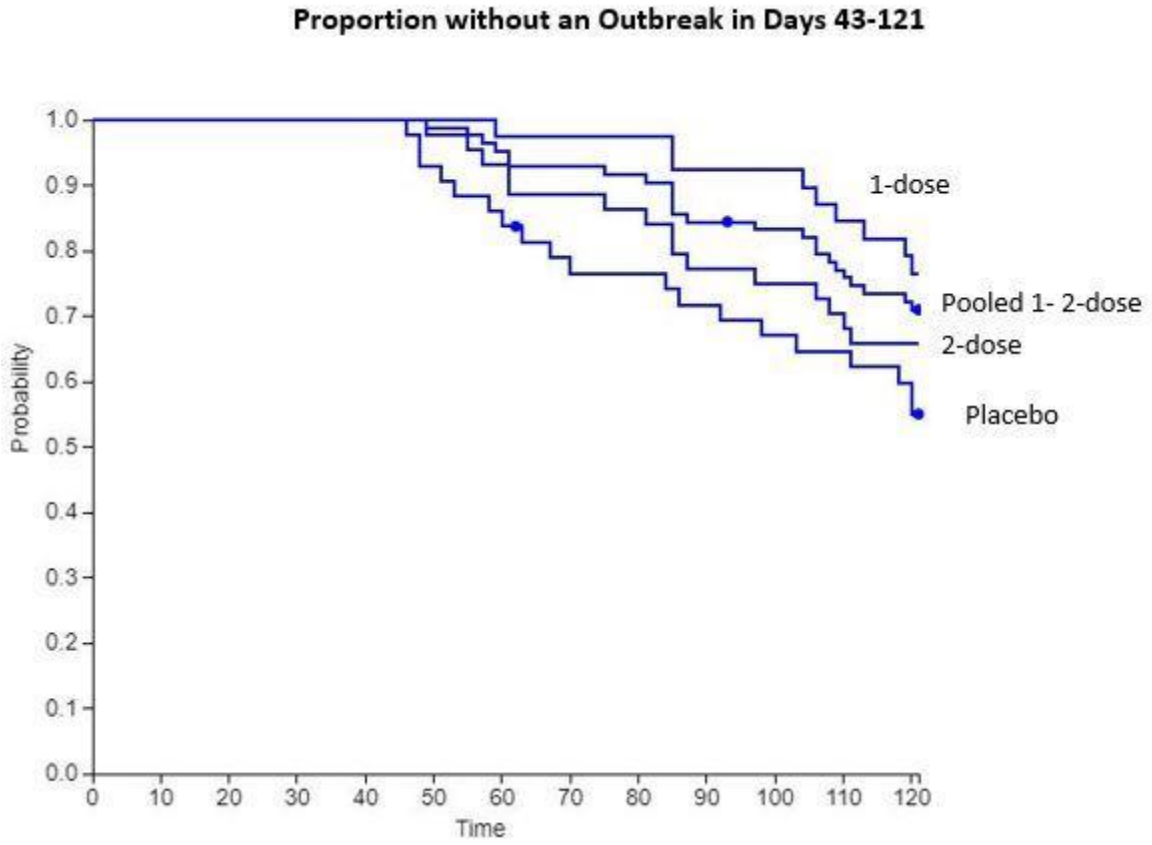
Methods: A multi-center vehicle-controlled double-blind randomized phase 2 clinical trial was conducted in subjects who reported four or more herpes labialis episodes in the previous 12 months. Subjects were randomized to receive either dimethylsulfoxide (DMSO) vehicle only on days 1 and 22, or 2% SADBE on day 1 and DMSO only on day 22 (one-dose group), or 2% SADBE on day 1 and a booster dose of 0.5% SADBE on day 22 (two-dose group).

Results: The primary endpoint was number of days until subject reported first new herpes labialis episode following sensitization dose on day 1 (Dose A). This endpoint was not met.

The other endpoints in order were (2) incidence of adverse events, (3) number of days until subject-reported first new herpes labialis episode following the intensification dose (Dose B, applied on day 22). This endpoint was not met. The next planned endpoint was number of days until subject-reported first new herpes labialis episode beginning from 21 days after the intensification dose (Dose B) (i.e., beginning from day 43). This endpoint was met. (P=0.024).

The 1-dose group was superior to the placebo group in time to next outbreak from day 43 to 121 (p=0.024) (Fig. 1), mean number of outbreaks in days 43-121 in 1-dose (0.231±0.125 standard error) vs. placebo (0.610±0.068) (p=0.011), and proportion of subjects with an outbreak in days 43-121 in 1-dose (9/39=23%) vs. placebo (19/41=46%) (p=0.036). Average number of moderate or severe outbreaks over days 43-121 was also reduced in subjects receiving 1 dose of SADBE (0.128±0.339) vs. placebo (0.390±0.703) (p=0.04), as well as over days 1-365 in 1-dose (0.641±0.931) vs. placebo (1.341±1.76) (p=0.04).

Fig. 1. Outbreak-free proportion by Kaplan-Meier method from day 43 to day 121 in the 1-dose group (n=41, 32 censored), pooled 1- and 2-dose groups (n=85, 61 censored), 2-dose group (n=44, 29 censored), and placebo group (n=43, 24 censored). 1-dose vs. placebo P=0.024, Hazard ratio with 95% confidence interval = 2.419 (1.094-5.351). Pooled 1- and 2-dose treatment groups vs. placebo P=0.049. Hazard ratio with 95% confidence interval = 1.814 (0.993-3.312) 2-dose vs. placebo P=0.29.



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The drug-treated groups had fewer outbreaks than the vehicle group throughout a 12-month follow up, but the largest effect was in days 43-121. This suggests that the drug takes about six weeks to exert maximal effect on the immune system, and the effects begin to taper off at about four months after the first dose. That fits with the data from the mechanism of action clinical trial discussed above. The one-dose group was significantly superior to the placebo group in time to the next outbreak in days 43-121, average number of outbreaks in days 43-121, proportion of subjects with an outbreak in days 43-121, and average number of moderate or severe outbreaks over days 43-121 and over days 1-365. The 2-dose group was also superior to the placebo group in all of those measures, but not significantly. In addition to having fewer outbreaks, the one-dose group had outbreaks that were less severe than the placebo group (0.3 versus 1.4 on severity score scale of 0 to 3).

The 2-dose regimen (dosing with 2% SQX770 on day 1 and 0.5% on day 22) was apparently less effective than the 1-dose regimen (2% on day 1 and 0% placebo on day 22). The reason could be just randomness, since the differences between the two groups did not reach statistical significance. But we think it is likely that the second dose at a lower concentration downregulated the immune responses caused by the first dose at the higher concentration. In the Phase 3 trials we plan to dose with a single concentration of SQX770, probably 2%, every three months.

Table I. Adverse events (AEs) scored by investigators as definitely, probably, or possibly study-medication related. All AEs were grade 1 (n=49) or grade 2 (n=6), with no grade 3 or higher AEs.

Adverse event	Placebo N = 47 subjects	SADBE: 1- or 2-dose N = 92 subjects
Administration site conditions		
Erythema	4	15
Itching or irritation	1	8
Tingling or stinging	4	-
Purpura	-	1
"Boil"	-	1
Subtotal	9	25
Tingling (not at administration site)	3	2
Flushing and burning sensation on face	-	3
Herpes lesion on genitals, anus, or spine	1	2
Dermatitis from bandage adhesive	2	-
Irritation or itching (not at administration site)	-	2
Rash (not at administration site)	-	1
Retention hyperkeratosis	-	1
Lightheadedness	1	-
Pimple	-	1
Papule on lip	-	1
Anemia	1	-
Total	**17**	**38**

Conclusion: A single topical dose of SQX770 applied topically to the upper arm significantly extended time to next herpes labialis outbreak and reduced the frequency of outbreaks and frequency of severe outbreaks in the period from 42 to 120 days after the dose and was very well tolerated in this study of 140 subjects with frequent herpes labialis outbreaks. These results confirm a previous vehicle-controlled clinical trial that showed a single topical dose of SQX770 on the arm delayed time to next herpes labialis outbreak[11], and a mechanism of action study that showed a single topical dose of SQX770 to the arm caused enhanced immune response to the HSV-1 virus[12].

Details and results of this clinical trial are found at:
https://clinicaltrials.gov/ct2/show/NCT02965781?term=NCT02965781&draw=2&rank=1

License Agreement

The original invention of a treatment that prevents oral herpes outbreaks that was the basis for Squarex was invented jointly by Dr. Hugh McTavish, who assigned his interest to Squarex, and Dr. Thomas D. Horn and Dr. Sandra M. Johnson, who were employees of the University of Arkansas for Medical Sciences. Dr. Horn and Dr. Johnson assigned their rights to BioVentures, LLC, the licensing arm of The Board of Trustees of the University of Arkansas. That invention was the basis for U.S. patent application no. 12/450,586, and continuations thereof, which are now U.S. Patents 9,205,065 and 10,744,084, and Korean Patent No. 10-2009-7023035.

We have an exclusive license for the rights belonging to BioVentures, LLC, (the licensing arm of the Board of Trustees of the University of Arkansas) in U.S. patent application no. 12/450,586, and continuations thereof, which are now U.S. Patents 9,205,065 and 10,744,084, and a Korean patent no. 10-2009-7023035. Under the terms of the license, Squarex will owe BioVentures (a) 5.5% of Net Sales by Squarex or its Affiliates (but not non-affiliated Sublicensees) during the Term and in the Territory of those three patents, and (b) 20% of all Sublicense Income based on a sublicense agreement executed before approval of a New Drug Application by the U.S. FDA sublicensing rights based on the two U.S. and one South Korean patents listed above (i.e., Sublicense Income received during the term of those patents and based on rights in the U.S. and South Korea) or 15% if the sublicense agreement is executed after approval of a

New Drug Application by the U.S. FDA. “Sublicense Income” includes signing fees and royalties on sales and other consideration received from a non-affiliated sublicensee for a sublicense. The patents expire in April 2028. BioVentures was also issued 150,000 shares in Squarex, representing, as of the date of this memorandum, approximately 4.1% of the Company’s issued and outstanding equity. No payments are due under the agreement for sales or events after the expiration of the patents.

We have the right to grant sublicenses consistent with the agreement. We were obligated to use reasonable commercial efforts to develop the Licensed Products or Processes, to deliver a business plan within 90 days, raise $200,000 within one year, develop a pharmaceutical composition within two years, and begin clinical trials within three years of the effective date of the agreement. We have met all of those obligations and met all of those milestones. Upon our failure to meet any of those obligations, BioVentures may give written notice of default and we have 45 days to cure the default.

In addition to the royalties listed above, we are obligated to pay BioVentures a Continuation Fee of $2,500 on each anniversary of the Effective Date. We have made eight such payments to date, totaling $20,000. In addition, we have reimbursed BioVentures for patent costs, totaling $42,912 to date. No development, regulatory, or commercial milestone payments are due to or have or will be paid to BioVentures under the agreement.

We have the right but not the obligation, at our own cost, to initiate patent infringement lawsuits and to defend the licensed patents against any challenges to their validity.

The license expires on a country-by-country basis on the date that the last of the claims of any licensed patent expires. That is expected to be on April 4, 2028. In addition, we have the right to terminate at any time upon 90 days written notice. BioVentures has the right to terminate the agreement only if we challenge the validity of any licensed patent.

Intellectual Property

Intellectual property, especially patents, are important to our business. We endeavor to establish, maintain and enforce intellectual property rights that protect our business interests.

Our patent portfolio, including patents owned by or exclusively licensed to us, is built on a program-by-program basis with a goal of establishing broad protection that generally includes, for each product candidate compound and for selected alternative back-up compounds, claims directed to composition of matter, pharmaceutical compositions, and methods of treatment using such pharmaceutical compositions. We are seeking and maintaining patent protection in the United States and key foreign jurisdictions.

[11] Palli, M. A., H. McTavish, A. Kimball, and T. D. Horn. 2017. Immunotherapy of Recurrent Herpes Labialis With Squaric Acid. *JAMA Dermatol*. 153:828-829.
[12] McTavish H, Zerebiec KW, Zeller JC, Shekels LL, Matson MA, Kren BT. 2019. Immune characteristics correlating with HSV-1 immune control and effect of squaric acid dibutyl ester on immune characteristics of subjects with frequent herpes labialis episodes. *Immun. Inflamm. Dis*. 7(1):22-40.

The term of individual patents depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may also be eligible for patent term adjustment, which permits patent term restoration as compensation for patent term lost during the regulatory review process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent per approved drug may be extended under the Hatch-Waxman Act. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term

extensions on patents covering those products. We plan to seek any available patent term extension to any issued patents we may be granted in any jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We also rely on trade secrets, especially relating to technical aspects of our manufacturing, formulations, and data and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Our trade secrets include, for example, aspects of the manufacturing of our drug, formulation, kits, and delivery device and patient selection and recruitment strategies, and certain proprietary data. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us, and for employees and consultants to enter into invention assignment agreements with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. It is our practice also to require our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ.

Upon approval in the United States, since SADBE has not previously been approved in the United States for any indication, it will be eligible for five years of new chemical entity exclusivity, which would run currently with patent exclusivity.

Furthermore, we will seek trademark protection in the United States and internationally where available and when we deem appropriate.

Patents

U.S. Patent No. 9,205,065. This patent has claims directed to a method of treating either genital or oral herpes comprising applying SADBE or similar contact sensitizers to a herpes lesion. It will expire in April 2028 or later with possible extensions of time for time spent in the FDA approval process. It is jointly assigned to Squarex and to BioVentures, LLC. Squarex has an exclusive license from BioVentures for BioVentures' portion of the patent. Dr. Hugh McTavish, our Chief Executive Officer, is a co-inventor of this patent and assigned his portion to Squarex.

U.S. Patent No. 10,744,084. This is in the same patent family as the U.S. 9,205,065 patent. It has claims directed to a pharmaceutical composition comprising SADBE dissolved in DMSO, which covers the SQX770 formulation as a composition of matter. It will expire in April 2028 or later with possible extensions of time for time spent in the FDA approval process. It is jointly assigned to Squarex and to BioVentures, LLC. Squarex has an exclusive license from BioVentures for BioVentures' portion of the patent. Dr. McTavish, our Chief Executive Officer, is a co-inventor of this patent and assigned his portion to Squarex.

U.S. Patent No. 10,245,314 and ***U.S. Patent No. 10,940,197*** are in the same patent family and both have claims directed to a method of treating either genital or oral herpes comprising applying SADBE or similar contact sensitizers topically to a site other than to a herpes lesion. They will expire in February 2036 or later with possible extension of time for time spent in the FDA approval process. They are owned exclusively by Squarex. Dr. McTavish, our founder and Chief Executive Officer, is the sole inventor of these patents and assigned them to Squarex.

A Korean patent is issued in the same family as the U.S. 9,205,065 and 10,744,084 patents. It will expire in April 2028. It is jointly assigned to Squarex and to BioVentures, LLC. Squarex has an exclusive license from BioVentures for BioVentures' portion of the patent.

Foreign patents corresponding to U.S. Patent No. 10,245,314 and U.S. Patent No. 10,940,197 are issued in Canada, Australia, Japan, the U.K., Ireland, Germany, France, Switzerland, and the Netherlands. A corresponding patent application is pending in South Korea.

U.S. patent application serial no. 17/194,832, publication no. 20210186863. Another method of treatment patent application is pending in the U.S. for using SADBE or similar compounds to treat molluscum contagiosum, a common contagious viral skin disease. This is owned exclusively by Squarex. If issued, the patent would expire in September 2038.

U.S. patent application serial no. 16/932,111, publication no. 20210393542. This application has claims directed to kits and delivery devices that will be the commercial products that are sold comprising the SQX770 drug formulation. If issued, the patents in this family would expire in July of 2040 or later with possible extensions of time for time spent in the FDA approval process. An international application under the Patent Cooperation Treaty (PCT), number PCT/US21/37277, in this family has also been filed. Foreign national stage applications in the major markets will be filed based on this. This family of patent applications is owned exclusively by Squarex.

We expect that other patent applications will be filed to cover the Squarex products and methods of medical treatment using those products.

Sales and Marketing

We currently do not have a commercial organization for the marketing, sales and distribution of pharmaceutical products. We do not plan to develop our own sales and marketing capability. Our business strategy is to license to, or partner with, a larger pharmaceutical company that has existing capabilities for marketing, sales, and distribution, particularly with direct to consumer marketing and marketing to primary care providers.

Manufacturing

We currently rely, and expect to continue to rely, on third parties for the manufacture of SQX770 and any other product candidates we develop, as well as for future commercial manufacture of SQX770 and any other drugs that we may commercialize. We do not own or operate, and currently have no plans to establish, any manufacturing facilities.

In general, we plan to establish agreements with contract manufacturing organizations, or CMOs, for synthesis of the active pharmaceutical ingredient, or API, manufacturing of drug product comprising such API, as well as packaging, labeling and distribution.

Competition

There are no FDA-approved therapies for the indication of *preventing* herpes labialis outbreaks, the indication we are pursuing approval for.

Existing approved drugs for herpes labialis are approved for *treating* herpes labialis—meaning that they are to be taken at the first sign of an outbreak, and if taken soon enough reduce the duration of the treated outbreak. The principal approved drugs for treating herpes labialis are oral valacyclovir, oral acyclovir, topical acyclovir cream, and topical docosanol. None of these are approved for *preventing* herpes labialis outbreaks. Valacylovir (VALTREX®) is the most used of these and generates the most revenue. Its prescribing information states that in clinical trials it has reduced the duration of episodes by one day and that it has no effect or frequency of episodes or severity of episodes. Valacyclovir is approved for preventing genital herpes outbreaks and it is sometimes prescribed off-label for preventing oral herpes outbreaks.

No other drugs are currently listed in clinicaltrials.gov as in clinical trials for the indication of preventing herpes labialis outbreaks, whereas SQX770 has completed a Phase 1 and a Phase 2 trial and we have had an End-of-Phase-2 meeting with the FDA. Accordingly, we believe that we have a substantial head start on any competition for this indication.

Government Regulation

Government authorities in the United States at the federal, state, and local level, including the FDA, the FTC and the DEA, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, marketing and export and import of products such as those we market. For both currently marketed and future products, failure to comply with applicable regulatory requirements can, among other things, result in suspension of regulatory approval and possible civil and criminal sanctions. Regulations, enforcement positions, statutes and legal interpretations applicable to the pharmaceutical industry are constantly evolving and are not always clear. Significant changes in regulations, enforcement positions, statutes and legal interpretations could have a material adverse effect on our financial condition and results of operations.

Additionally, future healthcare legislation or other legislative proposals at the federal and state levels could bring about major changes in the affected health care systems, including statutory restrictions on the means that can be employed by brand and generic pharmaceutical companies to settle Paragraph IV patent litigations. We cannot predict the outcome of such initiatives, but such initiatives, if passed, could result in significant costs to us in terms of costs of compliance and penalties associated with failure to comply.

Pharmaceutical Regulation in the United States

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, Warning Letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug or a generic version of a previously approved drug, can be marketed in the United States.The process required by the FDA before a new drug may be marketed in the United States generally involves:

- Completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's current GLP regulations;
- Submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin in the United States;
- Approval by an IRB at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with the FDA to establish the safety and efficacy of the proposed drug product for each intended use;
- Satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Submission to the FDA of an NDA;
- Satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA.

Preclinical Studies

When developing a branded product and bringing it to market, the first step in proceeding to clinical studies is preclinical testing. Preclinical tests are intended to provide a laboratory or animal study evaluation of the product to determine its chemistry, formulation and stability. Toxicology studies are also performed to assess the potential safety of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of these studies are submitted to the FDA as part of an IND application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it initiates at that institution. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their website, *www.ClinicalTrials.gov*.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase I: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- Phase II: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase III: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2, and Phase 3 trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on *www.ClinicalTrials.gov*. Information related to the product, subject population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss certain results of their clinical trials after completion.

Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Marketing Approval

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include, among other things, the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer or sponsor under an approved NDA is also subject to annual program fees. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, as amended, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that are intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over existing therapies. The FDA endeavors to review most applications subject to Standard Review within ten to twelve months whereas the FDA's goal is to review most Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. Before approving an NDA, the FDA may inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the NDA unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the NDA contains data that provide substantial evidence that the drug is safe and effective for the labeled indication.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter to indicate that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Moreover, as a condition of product approval, the FDA may require substantial post-approval testing, known as Phase IV testing, and/or surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or certain problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic safety reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in a manner consistent with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. There also are extensive DEA regulations applicable to controlled substances.

Adverse event reporting and submission of periodic reports is also required following FDA approval of an NDA. Additionally, the FDA may place conditions on an approval, in addition to REMS programs of Phase IV testing, that could restrict the distribution or use of the product. Drug manufacturers and certain of their subcontractors are required to register their establishments and list their marketed products with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs, including quality control and manufacturing processes. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, Warning Letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

The Hatch-Waxman Amendments

505(b)(2) NDAs

The FDA is authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the data owner.

The applicant may rely upon the FDA's findings of safety and efficacy for an approved product that acts as the "listed drug." The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve the new product candidate for all, or some, of the conditions of use for which the branded reference drug has been approved, or for a new condition of use sought by the 505(b)(2) applicant.

Abbreviated New Drug Applications ("ANDAs")

The Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of listed drugs. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient ("API\I"), drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include clinical data to demonstrate safety and effectiveness. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the reference listed drug. For some drugs, other means of demonstrating bioequivalence may be required by the FDA, especially where rate or extent of absorption are difficult or impossible to measure. The FDA will approve an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the reference listed drug. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the reference listed drug if it is intended for a different use or if it is not subject to, and requires, an approved Suitability Petition.

Patent Exclusivity and Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA (i) that there is no patent listed with the FDA as covering the relevant branded product, (ii) that any patent listed as covering the branded product has expired, (iii) that the patent listed as covering the branded product will expire prior to the marketing of the generic product, in which case the ANDA will not be finally approved by the FDA until the expiration of such patent or (iv) that any patent listed as covering the branded drug is invalid or will not be infringed by the manufacture, sale or use of the generic product for which the ANDA is submitted. A notice of the Paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the Paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the Paragraph IV certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug.

For example, a drug that is considered a new chemical entity (NCE) at the time of approval may be awarded a five-year period of marketing exclusivity, starting at the time of product approval. An ANDA or 505(b)(2) application referencing that drug may not be approved until the five-year period expires. Also, an ANDA or 505(b)(2) application referencing that drug may not be filed with the FDA until the expiration of five years, unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant.

Pricing and Reimbursement

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payor reimbursement for the cost of our products. Government authorities and third-party payors increasingly are challenging the price of medical products and services. On the government side, there is a heightened focus, at both the federal and state levels, on decreasing costs and reimbursement rates for Medicaid, Medicare and other government insurance programs. This has led to an increase in federal and state legislative initiatives related to drug prices, which could significantly influence the purchase of pharmaceutical products, resulting in lower prices and changes in product demand. If enacted, these changes could lead to reduced payments to pharmaceutical manufacturers. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If our current products or future drug candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe them to their Medicaid patients, thereby diminishing the potential market for our products.

In addition, third-party payors have been imposing additional requirements and restrictions on coverage and limiting reimbursement levels for pharmaceutical products. Third-party payors may require manufacturers to provide them with predetermined discounts from list prices and limit coverage to specific pharmaceutical products on an approved list, or formulary, which might not include all of the FDA-approved pharmaceutical products for particular indications. Third-party payors may challenge the price and examine the medical necessity and cost-effectiveness of pharmaceutical products in addition to their safety and efficacy. Manufacturers may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of pharmaceutical products in addition to the costs required to obtain the FDA approvals. Adequate third-party reimbursement may not be available to enable manufacturers to maintain price levels sufficient to realize an appropriate return on their investment in drug development.

Healthcare Reform

In the United States, there have been a number of federal and state proposals during the last several years regarding the pricing of pharmaceutical products, government control and other changes to the healthcare system of the United States. It is uncertain what other legislative proposals may be adopted or what actions federal, state, or private payors may take in response to any healthcare reform proposals or legislation. We cannot predict the effect such reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

By way of example, in March 2010, the ACA was signed into law, which, among other things, includes changes to the coverage and payment for drug products under government healthcare programs. The law includes measures that (i) significantly increase Medicaid rebates through both the expansion of the program and significant increases in rebates, (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts, (iii) extend the Medicaid rebate rate to a significant portion of Managed Medicaid enrollees, (iv) assess a rebate on Medicaid Part D spending in the coverage gap for branded and authorized generic prescription drugs, and (v) levy a significant excise tax on the industry to fund the healthcare reform.

In addition to the changes brought about by the ACA, other legislative changes have been proposed and adopted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. At the federal level, the Biden Administration is expected to release proposals on drug pricing, which may permit Medicare Part D plans to negotiate the price of all or certain drugs that those plans cover. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Healthcare Regulations

Pharmaceutical companies are subject to various federal and state laws that are intended to combat health care fraud and abuse and that govern certain of our business practices, especially our interactions with third-party payors, healthcare providers, patients, customers and potential customers through sales and marketing or research and development activities. These include anti-kickback laws, false claims laws, sunshine laws, privacy laws and FDA regulation of advertising and promotion of pharmaceutical products.

Anti-kickback laws, including the federal Anti-Kickback Statute, make it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referral of an individual for, or the purchase, order or recommendation of, any good or service reimbursable by, a federal health care program (including our products). The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The penalties for violating the federal Anti-Kickback Statute include administrative civil money penalties, imprisonment for up to five years, fines of up to $25,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit knowingly presenting, or causing to be presented, claims for payment to the federal government (including Medicare and Medicaid) that are false or fraudulent (and, under the Federal False Claims Act, a claim is deemed false or fraudulent if it is made pursuant to an illegal kickback). Manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in significant monetary penalties, including fines ranging from $11,181 to $22,363 for each false claim, and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other improper sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The Federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to $15,270 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal healthcare programs.

Federal criminal statutes prohibit, among other actions, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Analogous state and foreign laws and regulations, including state anti-kickback and false claims laws, may apply to products and services reimbursed by non-governmental third-party payors, including commercial payors. Additionally, there are state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or that otherwise restrict payments that may be made to healthcare providers as well as state and foreign laws that require drug manufacturers to report marketing expenditures or pricing information.

Sunshine laws, including the Federal Open Payments law enacted as part of the ACA, require pharmaceutical manufacturers to disclose payments and other transfers of value to physicians and certain other health care providers or professionals, and in the case of some state sunshine laws, restrict or prohibit certain such payments. Pharmaceutical manufacturers are required to submit reports to the government by the 90th day of each calendar year. Failure to submit the required information may result in civil monetary penalties of up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations. Certain states and foreign governments require the tracking and reporting of gifts, compensation and other remuneration to physicians.

Privacy laws, such as the privacy regulations implemented under HIPAA, restrict covered entities from using or disclosing protected health information. Covered entities commonly include physicians, hospitals and health insurers from which we may seek to acquire data to aid in our research, development, sales and marketing activities. Although pharmaceutical manufacturers are not covered entities under HIPAA, our ability to acquire or use protected health information from covered entities may be affected by privacy laws. Specifically, HIPAA, as amended by HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information.

Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

The FDA regulates the sale and marketing of prescription drug products and, among other things, prohibits pharmaceutical manufacturers from making false or misleading statements and from promoting products for unapproved uses. There has been an increase in government enforcement efforts at both the federal and state level.

Numerous cases have been brought against pharmaceutical manufacturers under the Federal False Claims Act, alleging, among other things, that certain sales or marketing-related practices violate the Anti-Kickback Statute or the FDA's regulations, and many of these cases have resulted in settlement agreements under which the companies were required to change certain practices, pay substantial fines and operate under the supervision of a federally appointed monitor for a period of years. Due to the breadth of these laws and their implementing regulations and the absence of guidance in some cases, it is possible that our practices might be challenged by government authorities. Violations of fraud and abuse laws may be punishable by civil and criminal sanctions including fines, civil monetary penalties, as well as the possibility of exclusion of our products from payment by federal health care programs.

Government Price Reporting

Government regulations regarding reporting and payment obligations are complex, and we will continually evaluate the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs when we have a marketed drug. Our calculations are subject to review and challenge by various government agencies and authorities, and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to such agency or the amounts themselves. Because the process for making these calculations, and our judgments supporting these calculations, involve subjective decisions, these calculations are subject to audit. In the event that a government authority challenges or finds ambiguity with regard to our report of payments, such authority may impose civil and criminal sanctions, which could have a material adverse effect on our business. From time to time we conduct routine reviews of our government pricing calculations. These reviews may have an impact on government price reporting and rebate calculations used to comply with various government regulations regarding reporting and payment obligations.

Many governments and third-party payors reimburse the purchase of certain prescription drugs based on a drug's AWP. In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, which they have suggested have led to excessive payments by state and federal government agencies for prescription drugs. Numerous pharmaceutical companies have been named as defendants in various state and federal court actions alleging improper or fraudulent practices related to the reporting of AWP.

Drug Pedigree Laws

State and federal governments have proposed or passed various drug pedigree laws which can require the tracking of all transactions involving prescription drugs from the manufacturer to the pharmacy (or other dispensing) level. Companies are required to maintain records documenting the chain of custody of prescription drug products beginning with the purchase of such products from the manufacturer. Compliance with these pedigree laws requires implementation of extensive tracking systems as well as heightened documentation and coordination with customers and manufacturers. While we fully intend to comply with these laws, there is uncertainty about future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our financial results.

Federal Regulation of Patent Litigation Settlements and Authorized Generic Arrangements

As part of the Medicare Prescription Drug Improvement and Modernization Act of 2003, companies are required to file with the U.S. Federal Trade Commission ("FTC") and the U.S. Department of Justice (the "DOJ") certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation or manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities.

Other

The U.S. federal government and various states and localities have laws regulating the manufacture and distribution of pharmaceuticals, as well as regulations dealing with the substitution of generic drugs for branded drugs. Our operations are also subject to regulation, licensing requirements and inspection by the states and localities in which our operations are located or in which we conduct business.

Certain of our activities are also subject to FTC enforcement actions. The FTC also enforces a variety of antitrust and consumer protection laws designed to ensure that the nation's markets function competitively, are vigorous, efficient and free of undue restrictions. Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us.

In addition, we are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances, the discharge of pollutants into the air and water and the cleanup of contamination. We are required to maintain and comply with environmental permits and controls for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased manufacturing activities at any of our facilities. We could incur significant costs or liabilities as a result of any failure to comply with environmental laws, including fines, penalties, third-party claims and the costs of undertaking a clean-up at a current or former site or at a site to which our wastes were transported. In addition, if we grow by acquisition in the future, and our diligence may not have identified environmental impacts from historical operations at sites we may acquire in the future.

Employees and Labor Relations

As of the date of this memorandum, we have a total of two full time employee and no part time employees. We have no collective bargaining agreements with our employees, and none are represented by labor unions. We consider our current relations with our employees to be good.

Facilities

We lease 2,000 square feet of space for our headquarters and laboratory in Saint Paul, Minnesota, under an agreement that, as amended, expires in June 2023. The current monthly lease payment is $4,185. We expect to lease separate office space in Saint Paul, Minnesota, within the next 12 months. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Legal Proceedings

From time to time we may be involved in claims that arise during the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

MANAGEMENT

Executive Officers and Directors

Below is a list of the names, ages, and positions of the individuals who serve as our executive officers and directors.

Name	Age	Position
Hugh McTavish, Ph.D.	60	Chairman, Chief Executive Officer, President and Chief Scientist
Constantine Kardaras, MBA, CPA	65	Chief Financial Officer
Arkadiusz Dudek, M.D.	58	Director
Wayne I. Danson	68	Director
Michael Myers, Ph.D.	61	Director
Mark W. Schwartz, Ph.D.	67	Director

Hugh McTavish, Ph.D., is a co-founder of the Company. He has been our Chairman, Chief Executive Officer, President and Chief Scientist since the Company's inception in 2012. Since 2004, he has also been President of IGF Oncology, LLC, a company founded by him. He has also been a patent attorney in solo practice with his own firm McTavish Patent Firm for the past twenty years. He is also the co-inventor of the Company's technology. Dr. McTavish is the lead author of 18 referenced scientific publications, and the inventor of 21 issued patents. Dr. McTavish received his Ph.D. in biochemistry from the University of Minnesota in 1992, and his J.D. from the University of Minnesota in 2001. As inventor of the Company's lead technology and his background in biochemistry and as a patent lawyer, make him uniquely suitable for the functions in which he currently serves. Dr. McTavish is expected to spend working for the Company on a full-time basis.

Constantine Kardaras was appointed Chief Financial Officer of the Company in January 2023. Prior to joining the Company, he was the Executive Director and Chief Accounting Officer at Imunon, a publicly traded, clinical stage biotechnology company in Lawrenceville, New Jersey in 2022 and Corporate Controller of Neumentum, a clinical stage pharmaceutical company in 2021. Mr. Kardaras was Executive Director for Finance and Accounting at TRU Kids, the successor parent for the Toys "R" Us brands from 2019 to 2021. Prior thereto, he consulted for publicly traded companies including Amicus Therapeutics, UGI Corporation, AIG, and Time Inc. from 2013 to 2019. Mr. Kardaras was also a senior manager at Deloitte from 2007 to 2013 where he advised Fortune 500 companies on finance transformation and IPO readiness. Mr. Kardaras is a CPA who holds an MBA in Finance from New York University's Stern School of Business and a BA in Economics from Connecticut College.

Arkadiusz Dudek, M.D. Ph.D., has been a director of the Company since 2018. Since 2015, he has held various positions, including President, Chief Executive Officer, and Chief Medical Officer at TTC Oncology, whose mission is to develop and bring to market a novel, small-molecule therapy to address unmet needs of breast cancer patients. Since 2019, he has been Chief Medical Officer of Luminary Therapeutics, a developer of a non-viral cell therapy for cancer and autoimmune disorders. He was also a director of Martell Diagnostic Laboratories from 2014 to 2021 and Chief Medical Officer of Vanquish Oncology, Inc. from 2013 to 2020. Dr. Dudek holds a medical degree from the Medical University, Warsaw. He completed his residency in internal medicine at the Pinnacle Health Hospitals in Harrisburg, Pennsylvania. His fellowship in oncology and hematology was at the University of Minnesota. Because of his medical and scientific background and his experience as an executive of pharma companies, we believe that he is highly qualified to be a Director.

Wayne I. Danson was elected to our board in November 2022. He has been Chief Financial Officer of EOM Pharmaceutical Holdings, Inc. since December 1, 2021. Since 1999, he has been President and Chief Executive Officer of Danson Partners, LLC, a financial advisory and business consulting firm, specializing in corporate finance, mergers and acquisitions, business strategy, management consulting, interim Chief Executive Officer/Chief Financial Officer and turnaround consulting, as well as sophisticated tax services. From 2004 to 2010, he was President, Chief Executive Officer and Director of Encompass Group Affiliates, Inc., a publicly traded logistics organization that he founded. Prior to forming Danson Partners, LLC, he held partnership and leadership positions with PricewaterhouseCoopers (in NY and Washington, D.C.) and Kenneth Leventhal & Co (in NY and Washington, D.C.), now Ernst & Young,

where he was a Managing Tax Partner. Mr. Danson previously served as Chairman of the Board of Directors for Encompass Group Affiliates, Inc. and a director of Herborium Group, Inc., both publicly traded small cap companies. He is Chairman of the Board of The Child Foundation, a 501(c)(3) charitable organization established to raise awareness of and funds to develop cures for all forms of children's interstitial and diffuse lung diseases. Mr. Danson graduated with honors from Bernard M. Baruch College with a BBA in Accounting and was an MBA candidate in Taxation. He is a certified public accountant and a member of the American Institute and New York State Societies of Certified Public Accountants. With his broad financial background and experience as a public company executive in the pharmaceutical and other industries, we believe that he is qualified to be a member of the Board of Directors.

Michael Myers, Ph.D., was elected to our board in November 2022. Dr. Myers is the co-founder and has served as director and Chief Executive Officer of Quoin Pharmaceuticals Ltd., an Israeli Nasdaq traded clinical stage, emerging specialty pharmaceutical company, since its inception in 2018. Dr. Myers has 35 years of industry experience in the drug delivery and specialty pharmaceutical sectors. He has served as Chief Executive Officer of Innocoll, Inc. and was responsible for taking that company public in 2014. During his tenure as Chief Executive Officer of Innocoll, Dr. Myers raised over $160 million in public and private funding and was the inventor of the company's lead commercial product. He has also served as President of the drug delivery division of West Pharmaceutical Services, President of pharmaceutical operations for Fuisz Technologies (Biovail) and has held executive positions in Flamel Technologies and Elan Corporation. He is listed as an inventor on numerous patents and has led the development and commercialization of a number of highly successful pharmaceutical products. Dr. Myers earned his Ph.D. in Chemistry from the University College Cork, Ireland. Dr. Myers serves on the Board of Directors of Sonoran Bioscience and Wellesley Pharmaceuticals in addition to the Board of Advisers for a number of Penn State start-up companies. Because of his medical and scientific background and his experience as an executive of pharma companies, we believe that he is highly qualified to be a Director.

Mark W. Schwartz, Ph.D., was elected to our board in November 2022. He is currently the Chairman of MWS Strategic Advisors LLC, serving as an adviser to several early-stage biotechnology and medical device companies. From 2001 to 2017 Dr. Schwartz served as Chief Executive Officer of several biotechnology companies including Calyx Therapeutics, Bayhill Therapeutics, Apthera and Galena Biopharma. Dr. Schwartz also serves as adjunct faculty at San Jose State University with appointments in the Masters in Biotechnology Program, the Lucas School of Management in the Business College, and the department of Biology. Dr. Schwartz holds a Ph.D. in Biochemistry from Arizona State University and a B.A. in Chemistry from Grinnell College. Because of his medical and scientific background and his experience as an executive of pharma companies, we believe that he is highly qualified to be a Director.

Directors are elected to serve until the next annual meeting of stockholders and until their successors are elected and qualified. A majority of the authorized number of directors constitutes a quorum of the Board of Directors for the transaction of business. The directors must be present at the meeting to constitute a quorum. However, any action required or permitted to be taken by the Board of Directors may be taken without a meeting if all members of the Board of Directors individually or collectively consent in writing to the action.

Family Relationships

None of our Directors are related by blood, marriage, or adoption to any other Director, executive officer, or other key employees.

CORPORATE GOVERNANCE

Board Leadership Structure

The Board of Directors is currently chaired by Dr. Hugh McTavish, who is our President and Chief Executive Officer. The Company believes that combining the positions of Chief Executive Officer and Chairman of the Board of Directors helps to ensure that the Board of Directors and management act with a common purpose. The Company also believes that it is advantageous to have a Chairman who is a co-founder of the Company and who, therefore, has knowledge of the Company's history. Notwithstanding the combined role of Chief Executive Officer and Chairman, key strategic initiatives and decisions involving the Company are discussed and approved by the entire Board of Directors. The Company believes that the current leadership structure and processes maintains an effective oversight of management and independence of the Board of Directors as a whole without separate designation of a lead independent director. However, the Board of Directors will continue to monitor its functioning and will consider appropriate changes to ensure the effective independent function of the Board of Directors in its oversight responsibilities.

Independence of the Board of Directors and its Committees

After review of all relevant transactions or relationships between each director, or any of his or her family members, and the Company, its senior management and its Independent Registered Public Accounting Firm, the Board of Directors has determined that a majority of the Company's directors are independent within the meaning of the NASDAQ listing standards. Wayne Danson, Michael Myers, Mark Schwartz, and Arkadiusz Dudek are deemed independent directors.

The Board of Directors has three committees: the Audit Committee, the Compensation Committee and the Nominating Committee. Below is a description of each committee of the Board of Directors. The Board of Directors has determined that each member of each committee meets the applicable rules and regulations regarding "independence" and that each member is free of any relationship that would interfere with his or her individual exercise of independent judgment with regard to the Company.

Audit Committee

The Audit Committee of the Board of Directors oversees the Company's corporate accounting and financial reporting process. For this purpose, the Audit Committee performs several functions. The Audit Committee, among other things: evaluates the performance, and assesses the qualifications, of the Independent Registered Public Accounting Firm; determines and pre-approves the engagement of the Independent Registered Public Accounting Firm to perform all proposed audit, review and attest services; reviews and pre-approves the retention of the Independent Registered Public Accounting Firm to perform any proposed, permissible non-audit services; determines whether to retain or terminate the existing Independent Registered Public Accounting Firm or to appoint and engage a new independent registered Public Accounting Firm for the ensuing year; confers with management and the Independent Registered Public Accounting Firm regarding the effectiveness of internal control over financial reporting; establishes procedures as required under applicable law, for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; reviews the financial statements to be included in the Company's Annual Report on Form 10-K and the Company's periodic quarterly filings on Form 10-Q, recommends whether or not such financial statements should be so included; and discusses with management and the Independent Registered Public Accounting Firm the results of the annual audit and review of the Company's quarterly financial statements.

The Audit Committee is currently composed of three independent directors: Michael Myers, chair, Arkadiusz Dudek and Mark Schwartz.

The Board of Directors periodically reviews the NASDAQ listing standards' definition of independence for Audit Committee members and has determined that all members of the Company's Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A) of the NASDAQ listing standards and Rule 10A-3(b)(1) of the Securities Exchange Act, as amended). The Board of Directors has determined that Michael Myers qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board of Directors made a qualitative assessment of Mr. Myers' level of knowledge and experience based on a number of factors, including his formal education and his service in executive capacities having financial oversight responsibilities.

Compensation Committee

The Compensation Committee of the Board of Directors reviews, modifies and approves the overall compensation strategy and policies for the Company. The Compensation Committee, among other things, reviews and approves corporate performance goals and objectives relevant to the compensation of the Company's officers; determines and approves the compensation and other terms of employment of the Company's Chief Executive Officer; determines and approves the compensation and other terms of employment of the other officers of the Company; and administers the Company's stock option and purchase plans, pension and profit sharing plans and other similar programs.

The Compensation Committee is composed of three independent directors: Wayne Danson, chair, Michael Myers, and Arkadiusz Dudek.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has at any time been an employee of ours. None of our executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Nominating Committee

The Nominating Committee of the Board of Directors is responsible for, among other things, identifying, reviewing and evaluating candidates to serve as directors of the Company; reviewing, evaluating and considering incumbent directors; recommending to the Board of Directors for selection candidates for election to the Board of Directors; making recommendations to the Board of Directors regarding the membership of the committees of the Board of Directors, and assessing the performance of the Board of Directors.

The Nominating and Governance Committee is currently composed of three independent directors: Mark Schwartz, chair, Wayne Danson, and Arkadiusz Dudek.

All members of the Nominating Committee are independent (as independence is currently defined in Rule 5605(a)(2) of the NASDAQ listing standards).

The Nominating Committee has not established any specific minimum qualifications that must be met for recommendation for a position on the Board of Directors. Instead, in considering candidates for director the Nominating Committee will generally consider all relevant factors, including among others the candidate's applicable education, expertise and demonstrated excellence in his or her field, the usefulness of the expertise to the Company, the availability of the candidate to devote sufficient time and attention to the affairs of the Company, the candidate's reputation for personal integrity and ethics and the candidate's ability to exercise sound business judgment. Other relevant factors, including diversity, experience and skills, will also be considered. Candidates for director are reviewed in the context of the existing membership of the Board of Directors (including the qualities and skills of the existing directors), the operating requirements of the Company and the long-term interests of its stockholders.

The Nominating Committee considers each director's executive experience and his or her familiarity and experience with the various operational, scientific and/or financial aspects of managing companies in our industry.

With respect to diversity, the Nominating Committee seeks a diverse group of individuals who have executive leadership experience and a complementary mix of backgrounds and skills necessary to provide meaningful oversight of the Company's activities. The Company meets the proposed NASDAQ standards for diversity on the board of directors. The Nominating Committee annually reviews the Board's composition in light of the Company's changing requirements. The Nominating Committee uses the Board of Directors' network of contacts when compiling a list of potential director candidates and may also engage outside consultants. Pursuant to its charter, the Nominating Committee will consider, but not necessarily recommend to the Board of Directors, potential director candidates recommended by stockholders. All potential director candidates are evaluated based on the factors set forth above, and the Nominating Committee has established no special procedure for the consideration of director candidates recommended by stockholders.

Code of Ethics

We have a Code of Ethics applicable to all of our officers, other employees and directors. The Code of Ethics is available on the Company's website.

Director Compensation

We are compensating our directors beginning as of January 1, 2023 with an annual director's fee of $30,000, and an annual Committee Chairman fee of $15,000, as well as $5,000 for each committee service. All fees will be payable in cash. Fees payable in cash will accrue and be payable upon the closing of this offering. In addition, each independent director was granted 40,000 stock options on January 1, 2023. Option grants for subsequent years will be determined by the Board.

EXECUTIVE COMPENSATION

SUMMARY COMPENSATION TABLE

The Summary Compensation Table shows certain compensation information for services rendered for the calendar years ended December 31, 2022 and December 31, 2021, by our executive officers. The following information includes the dollar value of base salaries, bonus awards, stock options grants and certain other compensation, if any, whether paid or deferred. Columns that are not applicable, have been omitted, as allowed under the relevant rules.

Name and Principal Position	Year	Salary	* All Other Compensation	Total
		($)	($)	($)
Hugh McTavish	2022	-*	96,180	96,180
Chief Executive Officer	2021	-*	96,180	96,180
Joseph Cunningham**	2022	44,000	-	44,000
Chief Financial Officer	2021	20,000	-	20,000

*The Company has been accruing salary for Dr. McTavish at the monthly rate of $8,015 for the two fiscal years.
** Mr. Cunningham left the Company in November 2022.

Our other executive officers have elected not to receive compensation during the recent reporting periods and no other persons are required to be disclosed in the summary compensation table.

We did not issue any stock option, warrants or Equity Incentive Awards to management in 2022 or 2021.

Employment Agreements

Hugh McTavish

Hugh McTavish, our Chief Executive Officer, performs his services pursuant to an employment agreement dated January 1, 2023. Under the terms of the agreement, Dr. McTavish is paid a monthly salary of $8,015 until the date of this initial public offering or other funding event resulting in $5 million or more funding for the Company, and thereafter paid an annual salary of $315,000. He is eligible for an annual bonus at the discretion of the Board of Directors of 30% to 40% of his annual salary. He was also granted 100,000 options at an exercise price of $1.00 on January 1, 2023, with one-third vesting immediately and the remaining two-thirds over a 3-year period.

The agreement has a term of two years and renews automatically for one-year periods unless either party terminates the agreement at least 90-days prior to the expiration of the agreement.

The agreement includes standard restrictive covenants for the duration of the term of the agreement and for the one-year period thereafter.

Constantine Kardaras

Constantine Kardaras, our Chief Financial Officer, performs his services pursuant to an employment agreement dated January 23, 2023. Under the agreement, Mr. Kardaras is paid an annual salary of $275,000 and is eligible for an annual bonus at the discretion of the Board of Directors of 30% to 40% of his annual salary. He was also granted 150,000 options at an exercise price of $1.00 on January 23, 2023, with one-third vesting immediately and the remaining two-thirds over a 3-year period.

The agreement has a term of two years and renews automatically for one-year periods unless either party terminates the agreement at least 90-days prior to the expiration of the agreement.

The agreement includes standard restrictive covenants for the duration of the term of the agreement and for the one-year period thereafter.

Equity Incentive Plan

On January 16, 2023, the Company's Board and the stockholders approved the adoption of the Company's 2023 Equity Incentive Plan (the "Plan") and reserved 1,700,000 shares of common stock for issuance under the Plan. Pursuant to the Plan, a committee appointed by the Board of Directors may grant, at its discretion, qualified or nonqualified stock options, stock appreciation rights and may grant or sell restricted stock to key individuals, including employees, nonemployee directors, consultants, and advisors. As of March 14, 2023, 100,000 options had been granted to the Chief Executive Officer, 150,000 to the Chief Financial Officer Mr. Kardaras, and 160,000 had been granted collectively to the four independent directors. These options were all granted in January 2023, under a vesting schedule of one-third vesting immediately and the remaining two-thirds over a 3-year period.

Limitation of Directors Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholder for monetary damages for breach of their fiduciary duties. The Certificate of Incorporation limits the liability of our directors to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with all of our directors and named executive officers whereby we have agreed to indemnify those directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of ours, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, our best interests.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act. The Certificate of Incorporation and bylaws also provide that we indemnify our directors and officers who, by reason of the fact that he or she is or was one of our officers or directors of our Company, is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative related to their board role with us.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2021, to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive Management- Executive Compensation." We also describe below certain other transactions with our directors, executive officers, and stockholders.

As of December 31, 2022, we owed our Chief Executive Officer $488,509 in principal and $163,000 in accrued interest in connection with loans advanced by him since October 1, 2019. The line of credit accrues interest at an annual rate of 15%. Under the terms of the arrangement, as cash comes into the Company from investments or loans from other sources, the Company will pay 10% of the first $1 million raised from other sources after January 1, 2021, 20% of the second $1 million, and up to 100% of the third $1 million raised from other sources after January 1, 2021, until the indebtedness is repaid in full. The balance is due and payable in full by December 31, 2024.

Our Chief Executive Officer is also owed $312,585 in back pay at the rate of $8,015 per month from October 2019 to December 2022. That balance is not accruing interest. Prior to the Company's conversion from a limited liability company to a corporation on September 13, 2022, Dr. McTavish was a consultant for the company. On September 13, 2022, Dr. McTavish became an employee of the Company.

Since 2019, we have paid our Chief Executive Officer through McTavish Patent Firm, an aggregate of $47,588 for legal fees in connection with patent applications.

SECURITIES OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information as of May 31, 2023, regarding the beneficial ownership of our Common Stock, based on information provided by (i) each of our executive officers and directors; (ii) all executive officers and directors as a group; and (iii) each person who is known by us to beneficially own more than 5% of the outstanding shares of our Common Stock. The percentage ownership in this table is based on 7,354,502 shares issued and outstanding as of April 4, 2023.

Unless otherwise indicated, we believe that all persons named in the following table have sole voting and investment power with respect to all shares of Common Stock that they beneficially own.

Name and Address of Beneficial Owner [1]	Amount and Nature of Beneficial Ownership of Common Stock	Percent of Common Stock
Hugh McTavish [2]	4,001,212	54.1%
Constantine Kardaras [3]	55,555	*
Arkadiusz Dudek [4]	351,309	4.8%
Wayne Danson [3]	15,555	*
Michael Myers [3]	15,555	*
Mark Schwartz [3]	15,555	*
Ronald L. Way	864,960	11.8
Sandra L. McTavish **6215 Hyland Ave.** **Lakeville, MN 55044**	762,612	10.4%
Thomas D. Horn **22 Liberty Drive #8F** **Boston, MA 02210**	819,000	11.1%
All Directors and Executive Officers as a Group (6 persons)	4,454,741	59.3%

(*) Less than 1%.

(1) Unless otherwise indicated, the address for each person is c/o Squarex Pharmaceutical Corporation, 7460 Pinehurst Road Saint Paul, MN 55115.
(2) Includes 38,888 shares of common stock issuable upon exercise of options.
(3) Consists of shares of common stock issuable upon exercise of options.
(4) Includes 15,555 shares of common stock issuable upon exercise of options.

DESCRIPTION OF SECURITIES

The following description summarizes some of the terms of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated Certificate of Incorporation and Amended and Restated Bylaws, copies of which have been filed as exhibits to the registration statement of which this memorandum is a part.

Authorized Capitalization

We have 255,000,000 shares of capital stock authorized under our Certificate of Incorporation, consisting of 250,000,000 shares of common stock with a par value of $0.0001 per share and 5,000,000 shares of preferred stock with a par value of $0.0001 per share. As of April 4, 2023, we had 7,354,502 shares of common stock outstanding and no shares of preferred stock outstanding. Our authorized but unissued shares of common stock and preferred stock are available for issuance without further action by our stockholder, unless such action is required by applicable law or the rules of any stock exchange or automated quotation system on which our securities may be listed or traded in the future.

Common Stock

Holders of our common stock are entitled to such dividends as may be declared by our Board of Directors out of funds legally available for such purpose. The shares of common stock are neither redeemable nor convertible. Holders of common stock have no preemptive or subscription rights to purchase any of our securities.

Each holder of our common stock is entitled to one vote for each such share outstanding in the holder's name. No holder of common stock is entitled to cumulate votes in voting for directors.

In the event of our liquidation, dissolution or winding up, the holders of our common stock are entitled to receive pro rata our assets, which are legally available for distribution, after payments of all debts and other liabilities. All of the outstanding shares of our common stock are fully paid and non-assessable. The shares of common stock offered by this memorandum will also be fully paid and non-assessable.

Preferred Stock

Our Board of Directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more classes or series and to fix the designations, rights, preferences, privileges and restrictions thereof, without further vote or action by the stockholder. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such class or series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Anti-Takeover Effects of Delaware law and Our Certificate of Incorporation and Bylaws

The provisions of Delaware law, our Certificate of Incorporation and our Amended and Bylaws, described below may have the effect of delaying, deferring or discouraging another party from acquiring control of us.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholder, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Potential Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the Delaware General Corporation Law and subject to any limitations set forth in our certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

Jurisdiction

Our bylaws stipulate that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director or officer of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation arising pursuant to any provision of the DGCL or the Corporation's Certificate of Incorporation or Bylaws, or (iv) any action asserting a claim against the Corporation governed by the internal affairs doctrine.

However, with respect to actions brought to enforce any duty or liability created by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or the rules and regulations thereunder, Section 27 of the Exchange Act provides that federal district courts have exclusive jurisdiction. In addition, Section 22 of the Securities Act of 1933, as amended (the "Securities Act"), provides that legal actions alleging offenses and violations committed under the Securities Act or the rules and regulations thereunder may be brought in both federal district and state courts. There is uncertainty as to whether a court would enforce the forum designation included in our amended and restated bylaws.

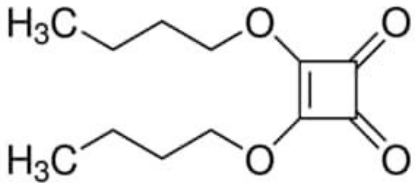
Accordingly, our bylaws provide exceptions to the Delaware forum requirement in any action brought by stockholders under the Securities Act or the Exchange Act.

Transfer Agent and Registrar

The transfer agent and registrar for our shares of common stock is VStock Transfer, LLC.

GLOSSARY OF TERMS USED

API.	Active Pharmaceutical Ingredient. The molecule in a pharmaceutical formulation that causes the therapeutic effect.
CMO	Contract Manufacturing Organization. A third party that manufactures drug products and drug substances for pharmaceutical companies.
DMSO	Dimethylsulfoxide. The carrier for our SQX770 formulation.
Drug substance	An active ingredient that is intended to furnish pharmacological activity.
Drug product	A finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.
FDA	U.S. Food and Drug Administration.
FDCA	Federal Food, Drug, and Cosmetic Act.
GCP	Good clinical practices. It refers to the requirements for documentation and standards for conducting clinical trials. cGCP refers to current good clinical practices, as the required standards evolve.
GLP	Good laboratory practices. It refers to the requirements for documentation and the standards for laboratory testing and practice in support of a New Drug Application. cGLP refers to current good laboratory practices, as the required standards evolve.
GMP	Good manufacturing practices. It refers to the requirements for documentation and the standards for manufacturing of drugs and devices for medical use. cGMP refers to current good manufacturing practices, as the required standards evolve.
HSV	Herpes simplex virus. HSV type 1 is HSV-1 and type 2 is HSV-2. HSV-1 usually causes oral herpes or herpes labialis and HSV-2 usually causes genital herpes or herpes genitalis.
IFNG	Interferon gamma, a cytokine or chemical messenger that is secreted by certain cells, particularly T helper cells, and has effects on other immune cells. IFNG is a key antiviral cytokine and data shows that SADBE application in our clinical trials causes increased IFNG expression by white blood cells when they are exposed to HSV-1.
IgG	Immunoglobulin gamma, the predominant circulating blood form of antibodies. Anti-HSV-1 IgG refers to IgG that recognizes and binds to HSV-1.
IL5	Interleukin-5, a cytokine or chemical messenger that is secreted by certain cells, particularly T helper cells. IL5 stimulates an antibody immune response and shifts the immune response away from a cellular or T cell immune response. Our data shows SADBE topical application causes a decrease in IL5 expression by white blood cells when they are exposed to HSV-1 and that lower IL5 expression in that context correlates with fewer herpes labialis outbreaks and better immune control of the HSV-1 virus.
IND	Investigational New Drug application. A request from a study sponsor to the FDA for authorization to administer an investigational drug to humans. An IND must be approved by the FDA before commencing clinical trials for a new drug.
IRB	Institutional review board. An ethics board for a clinical site that approves clinical trials or experimentation on humans at that site.

NCE	New chemical entity. A drug that has never been previously approved by the FDA as an Active Pharmaceutical Ingredient or API. NCE status brings some additional periods of exclusivity in the U.S. SADBE qualifies as an NCE.
NDA	New Drug Application. The application filed with the U.S. Food and Drug Administration for approval to market a drug. It is filed after completion of all clinical trials.
PBMC	Peripheral blood mononuclear cells. Cells in circulating blood that have a single nucleus. This is basically white blood cells and includes leukocytes and lymphocytes.
PCR	Polymerase chain reaction, a widely used laboratory method for amplifying DNA.
REMS	A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risk
SADBE	Squaric acid dibutylester, also known as dibutyl squarate or by its proper chemical name of 3,4-Dibutoxy-3-cyclobutene-1,2-dione. The chemical structure is below. 
SQX770	Squarex's code name for our drug formulation comprising SADBE dissolved in DMSO.
Th1	Type 1 T helper cells. A type of immune cell that secretes type 1 cytokines, which include IFNG.
Th2	Type 2 T helper cells. A type of immune cell that secretes type 2 cytokines, which include IL5.

SQUAREX PHARMACUETICAL CORPORATION

INDEX TO FINANCIAL STATEMENTS

FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2022 AND 2021 AND FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders

SquareX Pharmaceutical Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheet of SquareX Pharmaceutical Corporation (the Company) as of December 31, 2022, and the related statements of operations, change in stockholders' deficit, and cash flows the year ended December 31, 2022, and the related notes (collectively referred to as the "financial statements") . In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America. The financial statements of SquareX Pharmaceutical Corporation as of December 31, 2021, were audited by other auditors whose report dated July 8, 2022 expressed an unqualified opinion on those financial statements.

Going Concern

The accompanying financial statements have been prepared assuming the company will continue as a going concern. As discussed in Note 1 to the financial statements, the company has an accumulated deficit at December 31, 2022 and 2021 and has a working capital deficit at December 31, 2022, which raises substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB .

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and the significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe our audit provides a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Capital Stock and Other Equity Accounts

As discussed in Note 9, the Company issues common stock for services to non-employees.

Auditing management's calculation of the fair value of the common stock issued can be a significant judgment given the fact that the Company uses management's estimates on various inputs to the calculations.

To test the valuation of the common stock, we evaluated management's significant judgments and estimates. Significant judgements and estimates related to the fair valuing of the services for which the common stock was issued as consideration. We evaluated management's conclusions regarding their fair values and reviewed support for the significant inputs used. In addition, we evaluated the Company's disclosure in relation to this matter included in Note 9 to the financial statements.

s/ M&K CPAS, PLLC

M&K CPAS, PLLC

We have served as the Company's auditor since 2023

Houston, TX

March 28, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

FL Office
7951 SW 6th Street, Suite 216
Plantation, FL 33324
Tel: 954-424-2345
Fax: 954-424-2230

To the Board of Directors and Stockholders of
Squarex, LLC:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Squarex, LLC ("the Company") as of December 31, 2021 and December 31, 2020 and the related statements of operations, members' deficit, cash flows and the related notes to consolidated financial statements (collectively referred to as the consolidated financial statements) for the years ended December 31, 2021 and December 31, 2020. In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and December 31, 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB and Generally Accepted Audit Standards (GAAS). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has an accumulated deficit, recurring losses, and expects continuing future losses. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

The firm has served this client since January 2022.

/s/ L&L CPAS, PA

L&L CPAS, PA

Certified Public Accountants

Plantation, FL

The United States of America

July 8, 2022

SQUAREX PHARMACUETICAL CORPORATION
BALANCE SHEETS

	As of December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,177	$ 35,301
Right-of-use asset – current	14,982	26,782
Other current assets	3,497	10,500
Total current assets	23,656	72,583
Right-of-use asset – non-current	-	14,982
Total assets	**$ 23,656**	**$ 87,565**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 47,448	$ 53,304
Accounts payable, related party	12,070	441
Accrued liabilities, related party	355,283	259,103
Lease liability – current	15,231	26,782
Other current liabilities	35,505	28,573
Total current liabilities	465,537	368,203
Line of credit, related party	488,509	445,794
Accrued interest, related party	163,000	74,007
Convertible notes	50,000	-

Lease liability – non-current	-	15,231
Total liabilities	1,167,046	903,235
Mezzanine equity		
Simple agreement for future equity	235,067	-
Stockholders' deficit		
Common stock - $0.0001 par value (250,000,000 authorized shares; 7,354,502 and 7,342,502 issued and outstanding shares as of December 31, 2022 and December 31, 2021, respectively)	735	734
Preferred stock - $0.0001 par value (5,000,000 authorized and unissued shares)	-	-
Additional paid-in capital	6,877,000	6,883,351
Accumulated deficit	(8,256,192)	(7,699,755)
Total stockholders' deficit	**(1,378,457)**	**(815,670)**
Total liabilities, mezzanine equity and stockholders' deficit	**$ 23,656**	**$ 87,565**

See accompanying notes to financial statements.

SQUAREX PHARMACUETICAL CORPORATION
STATEMENTS OF OPERATIONS

	Year Ended December 31,	
	2022	**2021**
Operating expenses:		
Sales and marketing	$ 9,823	$ 4,150
Research and development	74,110	71,044
General and administrative	379,332	232,778
Total operating expenses	463,265	307,972
Loss from operations	**(463,265)**	**(307,972)**
Other income (expense):		
Interest expense, net	(4,179)	(3,250)
Interest expense - related party, net	(88,993)	(52,957)
Total other income (expense), net	(93,172)	(56,207)
Loss before income tax provision	**(556,437)**	**(364,179)**
Income tax provision	-	-
Net loss	**$ (556,437)**	**$ (364,179)**
Net loss per common share - basic and diluted	**$ (0.08)**	**$ (0.05)**
Weighted average common shares outstanding - basic and diluted	**7,346,250**	**6,819,187**

See accompanying notes to financial statements.

SQUAREX PHARMACUETICAL CORPORATION
STATEMENTS OF CHANGE IN STOCKHOLDERS' DEFICIT

	Common Stock Outstanding		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balances, as of December 31, 2020	**6,802,502**	**$ 680**	**$ 5,749,420**	**$ (7,335,576)**	**$ (1,585,476)**
Exercise of warrants	540,000	54	1,133,931	-	1,133,985
Net loss	-	-	-	(364,179)	(364,179)
Balances, as of December 31, 2021	**7,342,502**	**$ 734**	**$ 6,883,351**	**$ (7,699,755)**	**$ (815,670)**
Stock compensation expense	12,000	1	11,279	-	11,280
Issuance cost of SAFEs	-	-	(17,630)	-	(17,630)
Net loss	-	-	-	(556,437)	(556,437)
Balances, as of December 31, 2022	**7,354,502**	**$ 735**	**$ 6,877,000**	**$ (8,256,192)**	**$ (1,378,457)**

See accompanying notes to financial statements.

SQUAREX PHARMACUETICAL CORPORATION
STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (556,437)	$ (364,179)
Adjustments to reconcile net loss to net cash used in operating activities:		
Common shares issued for services	11,280	-
Incremental rent payment on operating lease	-	249
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	7,003	(10,500)
Accounts payable	5,773	53,745
Accrued liabilities, related party	96,180	109,183
Accrued interest, related party	88,993	52,958
Other current liabilities	6,932	(24,457)
Net cash used in operating activities	**$ (340,276)**	**$ (183,001)**
Cash flows from investing activities:		
Net cash used in investing activities	**$ -**	**$ -**
Cash flows from financing activities:		
Proceeds from issuance of SAFEs	$ 235,067	$ -
Issuance cost of SAFEs	(17,630)	-
Proceeds from issuance of convertible notes	50,000	-
Drawdown on line of credit, related party	122,865	159,793
Repayment on line of credit, related party	(80,150)	-
Proceeds from warrants exercised	-	54,000
Net cash provided by financing activities	**$ 310,152**	**$ 213,793**

Increase (decrease) in cash and cash equivalents	$	(30,124)	$	30,792
Cash and cash equivalents, beginning of the year	$	35,301	$	4,509
Cash and cash equivalents, end of the year	**$**	**5,177**	**$**	**35,301**

See accompanying notes to financial statements.

SQUAREX PHARMACUETICAL CORPORATION
NOTES TO FINANCIAL STATEMENTS

NOTE 1 – DESCRIPTION OF BUSINESS

Squarex Pharmaceutical Corporation ("Squarex" or the "Company") is a clinical stage pharmaceutical company that is developing a drug intended to improve immune function to reduce the severity and incidence of infectious diseases.

The Company was formed on June 26, 2012 as a limited liability company, organized under the laws of Delaware and domiciled in Minnesota. Effective September 13, 2022, the Company converted from a Delaware limited liability company to a Delaware corporation. The Company's staff are located in Minnesota and Pennsylvania with a laboratory facility located in Saint Paul, Minnesota.

Going Concern and Management's Liquidity Plans

The financial statements have been prepared assuming the Company will continue as a going concern, which assumes that the Company will continue in operation one year after the date the financial statements are issued. However, management has identified the following conditions and events that create an uncertainty about the ability of the Company to continue as a going concern.

The Company has incurred net losses since inception, including net losses of approximately $556,437 and $364,179 for the years ended December 31, 2022 and 2021, respectively, and expects to generate losses from operations for the foreseeable future primarily due to the costs for completing Phase 2 Bridging and Phase 3 clinical trials.

The Company raised $235,067 through a Regulation CF offering in 2022 (see Note 9, Stockholders' Deficit) and $54,000 from the exercise of all outstanding warrants of the Company in 2021. In addition, the Company may draw down on $1 million line of credit (see Note 6, Line of Credit, Related Party) which had an outstanding principal balance of $488,509 as of December 31, 2022. The Company believes that it has sufficient funds available to continue operations through the end of the fourth quarter of 2023.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying financial statements of Squarex have been prepared in accordance with generally accepted accounting principles in the U.S. and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting period. Actual results could differ from those estimates.

Reclassification

Certain amounts previously presented for prior periods have been reclassified to conform to the current presentation. The reclassifications had no effect on net loss, working capital or total equity previously reported.

Cash and Cash Equivalents

The Company considers cash in financial institutions and all highly liquid investments purchased with a maturity of three months or less at the date of acquisition to be cash and cash equivalents.

Concentration of Credit Risk

The Company maintains cash balances in one banking institution. The balances are insured by the Federal Deposit Insurance Company ("FDIC"). At times throughout the year, the Company's cash balances may exceed the limit insured by the FDIC. Management believes there is no significant risk of loss in having cash balances in excess of the insured limit.

Fair Value Measurements

Fair value is an exit price, representing the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants based on the highest and best use of the asset or liability. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The Company uses valuation techniques to measure fair value that maximize the use of observable inputs and minimize the use of unobservable inputs. These inputs are prioritized as follows:

- *Level 1* – Observable inputs, such as quoted prices for identical assets or liabilities in active markets.
- *Level 2* – Inputs, other than the quoted prices in active markets, which are observable either directly or indirectly, such as quoted prices for similar assets or liabilities, or market-corroborated inputs.
- *Level* 3 – Unobservable inputs for which there is little or no market data which require the reporting entity to develop its own assumptions about how market participants would price the assets or liabilities.

The Company's carries cash and cash equivalents, accounts payable, and accrued liabilities on the balance sheet at cost as a reasonable estimate that approximates the fair value of these items.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated over the estimated useful lives of the respective assets, using the double declining balance method. Assets with an expected useful life of less than one year or an original purchase price of less than $1,000 are expensed by the Company.

The Company's property and equipment consists of $59,349 in lab equipment that was purchased prior to 2022 and was fully depreciated as of December 31, 2021. As such, the Company's property and equipment, net of depreciation was nil as of December 31, 2022 and 2021, respectively.

Revenue Recognition

The Company's leading product is a drug in clinical trials for which parameters have been established with the FDA for progressing though to Phase 3 clinical trials. As such, the Company's drug is not yet available for sale to the public and no revenue has been recognized for the years 2022 and 2021.

Research and Development

Research and development costs are expensed as incurred and consist primarily of testing and developing costs, materials and supplies, consulting services and other direct expenses.

Contingencies

The Company follows subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies. Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company or unasserted claims that may result in such proceedings, the Company evaluates the perceived merits of any legal proceedings or unasserted claims as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed.

Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed. However, there is no assurance that such matters will not materially and adversely affect the Company's business, consolidated financial position, and consolidated results of operations or consolidated cash flows.

Net Loss Per Common Share

Basic and diluted net loss per common share was computed by dividing net loss for the year by the weighted average number of shares of common stock outstanding, both basic and diluted, during each period. The impact of common stock equivalents has been excluded from the computation of diluted weighted average common shares outstanding in periods where there is a net loss, as their effect is anti-dilutive.

Related Parties

Any person who is or was an executive officer, director or nominee for director of the Company, stockholder owning more than 5% of any class of the Company's voting securities or who can significantly influence the management or operating polices of the Company that might prevent the Company from fully pursuing its own separate interests, or an immediate family member of any such person, shall be considered a related party ("related party").

Any transaction, arrangement, or relationship (including any indebtedness or guarantee of indebtedness) or any series of similar transactions, arrangements, or relationships between the Company and a related party shall be considered a related party transaction, provided that there is a financial aspect to the transaction, including transactions that involve payments or providing value between the Company and the related party.

Income Taxes

Prior to the Company's conversion to a corporation on September 13, 2022, the Company elected to be treated as a pass-through entity for income tax purposes. Accordingly, taxable income and losses of the Company were reported

on the income tax returns of its members, and no provision for federal income taxes has been recorded in the accompanying financial statements for any periods prior to September 13, 2022. If the Company had been a taxable entity prior to the conversion date, the Company would not have recorded a provision for income taxes as the Company has sustained losses since its inception.

No income tax benefit has been recorded for the tax year ending December 31, 2022 for the net operating losses that incurred since Company's conversion to a corporation on September 13, 2022, due to the uncertainty of realizing a benefit from those items (See Note 14, Income Taxes). The Company accounts for income taxes under the liability method. Under this method deferred income tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and tax basis of assets and liabilities and for operating losses and tax credit carry forwards, using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that a portion or all of a deferred tax asset will not be realized.

The Company is subject to franchise tax filing requirements in the State of Delaware and state income tax filing requirements in the State of Minnesota.

Subsequent Events

The Company follows the guidance in Section 855-10-50 of the FASB Accounting Standards Codification for the disclosure of subsequent events. The Company will evaluate subsequent events through the date when the financial statements are issued.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB"), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Improvements (ASU 2020-10)

In October 2020, the FASB issued ASU No. 2020-10, Codification Improvements, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The updated guidance is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years.

The Company adopted ASU 2020-10 as of the reporting period beginning January 1, 2021. The Company has assessed that the adoption of this new standard did not have a material impact on our accompanying financial statements for the reporting periods of 2022 and 2021.

Debt Instruments (ASU 2020-06)

In August 2020, the FASB issued ASU No. 2020-06, Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)-Accounting For Convertible Instruments and Contracts in an Entity's Own Equity. The ASU simplifies accounting for convertible instruments by removing major separation models required under current GAAP. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The ASU also simplifies the diluted net income per share calculation in certain areas. The new guidance is effective for annual and interim periods beginning after

December 15, 2021, and early adoption is permitted for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years.

We have adopted ASU No. 2019-12 as of the reporting period beginning January 1, 2022. The Company has assessed that the adoption of this new standard did not have a material impact on our accompanying financial statements for the reporting periods of 2022 and 2021.

Income Taxes (ASU 2019-12)

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740) - Simplifying the Accounting for Income Taxes. ASU 2019-12 seeks to simplify the accounting for income taxes by updating certain guidance and removing certain exceptions. ASC 740 provides recognition criteria and a related measurement model for uncertain tax positions taken or expected to be taken in income tax returns. The guidance requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities. Tax positions that meet the more likely than not threshold are measured using a probability weighted approach recognizing the largest amount of tax benefit that is greater than 50% likely to being realized upon ultimate settlement. The updated guidance is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years.

The Company adopted ASU 2019-12 as of the reporting period beginning January 1, 2021. The Company has assessed that the adoption of this new standard did not have a material impact on our accompanying financial statements for the reporting periods of 2022 and 2021.

NOTE 3 – OTHER CURRENT ASSETS

The Company recorded prepaid expenses of $3,497 and $10,500 in “Other current assets” on the balance sheet as December 31, 2022, and 2021, respectively.

NOTE 4 – ACCRUED LIABILITIES, RELATED PARTY

Accrued liabilities payable to related parties total the following of December 31, 2022 and 2021:

	As of December 31,	
	2022	2021
Related party accrued liabilities for services	$ 326,429	$ 259,103
Related party accrued compensation	28,854	-
Accrued liabilities, related parties	$ 355,283	$ 259,103

Accrued liabilities with related parties included fees payable to the Company’s President who worked as an independent contractor in 2019 to 2022 and fees payable to a member of the Board of Directors for performing services for the Company in 2019 to 2021. In addition, employee compensation was accrued for the Company’s President once he became an employee in 2022.

NOTE 5 – FAIR VALUE MEASUREMENTS

The Company adopted ASC 820, Fair Value Measurements and Disclosures for all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the Combined financial statements on a recurring basis (at least annually). ASC 820 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

Financial instruments include cash, accounts payable and accrued liabilities, which were carried at cost as a reasonable estimate that approximates the fair value of these items.

NOTE 6 – LINE OF CREDIT, RELATED PARTY

On October 1, 2019, the Company established $1 million line of credit with a related party for the purpose of funding continuing operations ("Line of Credit"). The agreement stipulates a repayment arrangement as the Company obtains investor capital. An amount equal to 10% of the first $1 million, 20% of the second $1 million and up to 100% of the third $1 million dollars raised through investors is to be applied to the repayment of the Line of Credit. The Line of Credit accrues interest at 15% per annum with principal and interest payable no later than December 31, 2024. During 2022, the Company repaid $80,150 of principal from funds not currently being used for continuing operations.

The activities of the Line of Credit during year 2022 and 2021 are illustrated in the table below:

	Principal	Accrued Interest
Balance as of December 31, 2020	$ 286,001	$ 21,050
Drawdown	159,793	-
Interest Incurred	-	52,957
Balance as of December 31, 2021	$ 445,794	$ 74,007
Drawdown	122,865	-
Repayment	(80,150)	-
Interest Incurred	-	88,993
Balance as of December 31, 2022	$ 488,509	$ 163,000

NOTE 7 – CONVERTIBLE NOTES

In October 2022, the Company issued $50,000 in convertible notes (the "Convertible Notes") that have a 6% interest rate payable quarterly in arrears starting in the second quarter of 2023. Half of the principal on the Convertible Notes has a maturity date of October 24, 2025 with the remaining principal having a maturity date of October 26, 2027. In the event of an initial public offering ("IPO"), the Convertible Notes are converted into the Company's common stock at 15% discount to the price being offered to the public. The Convertible Notes are classified as long-term debt and appear on the balance sheet under the caption, "Convertible debt – non-current".

NOTE 8 – LEASES

As of June 1, 2020, the Company entered into a one-year sublease agreement with IGF Oncology, LLC ("IGF"), a company controlled by a related party, for the use of 994 square feet of laboratory space in St. Paul, Minnesota (the "Lab"). On June 21, 2021, the lease was the assigned to the Company (see Note 13, Related Party Transactions). The Company elected to apply the short-term lease exception to recognize the sublease payments in the statement of operations on a straight-line basis over the lease term.

On June 22, 2021, the assigned lease for the Lab was modified by extending the term for one year starting on July 1, 2021. The Company's expectation was that it would extend the lease for a second year at the end of the lease term. On June 2, 2022, the lease was extended to June 30, 2023, although the Company was uncertain on whether it would extend the lease past its termination date. Since the Company expected to lease the Lab for two years the lease was modified, the modified lease was not eligible for the short-term lease exception. As such, the modified lease was classified as a two-year operating lease beginning on July 1, 2021 where a right of use asset and a lease liability was recorded on the balance sheet.

Lease expenses are reported on the statement of operations in "General and administrative" as follows:

	Year Ended December 31,	
	2022	2021
Total lease expense	$ 43,232	$ 15,656

The following information for leases is reported on balance sheet:

	As of December 31,	
	2022	2021
Operating lease right-of-use assets	$ 14,982	$ 41,764
Current portion of the operating lease liabilities	$ 15,231	$ 26,782
Non-current portion of the operating lease liabilities	-	15,231
Total operating lease liability	$ 15,231	$ 42,013

Other supplemental operating lease information is listed in the following table:

	Year Ended December 31, 2022
Lease liability principal payments	$ 26,782
Lease amortized right of use asset	26,782
Total lease payments	31,311
Weighted average remaining life, as of year-end	0.5 years
Weighted average discount rate, as of year-end	15%

Future minimum operating lease payments are shown on the following table:

	As of December 31, 2022
2023 future lease payments	$ 15,904
Total future lease payments	15,904
Less: imputed interest	(673)
Total operating lease liability	$ 15,231

NOTE 9 – STOCKHOLDERS' DEFICIT

Corporate Structure

The Company was formed on June 26, 2012 as a limited liability company, organized under the laws of Delaware. On September 13, 2022, the Company converted from a limited liability company to a Delaware corporation. For the conversion, each outstanding limited liability company membership unit was automatically converted into two shares of common stock. The Company's financial statements report the conversion to a corporation on a retrospective basis.

Common Stock

As of December 31, 2022 and upon converting to a Delaware corporation on September 13, 2022, the Company had 250 million authorized shares of common stock and 5 million authorized shares of preferred stock.

As of December 31, 2022 and 2021, the Company had 7,354,502 and 7,342,502 shares of common stock issued and outstanding, respectively, and no issued or outstanding shares of preferred stock. In September 2022, the Board of Directors issued 12,000 shares of common stock to a consultant who provided services to the Company that were valued at $11,280. Dividends on common stock will be paid when, and if, declared by the Board of Directors. Each

holder of common stock is entitled to vote on all matters that are appropriate for stockholder voting and is entitled to one vote for each share held.

SAFEs

During the first quarter of 2022, the Company raised $235,067 from the issuance of Simple Agreement for Future Equity interests ("SAFEs"), net of $17,630 in issuance costs for the SAFEs. The SAFEs were issued to a group of investors in a crowd funding campaign under Regulation CF. The SAFEs do not earn interest and do not have a maturity date. In the event of an IPO, investors in the SAFEs will be issued shares of the Company's common stock at 30% discount to the price being offered to the public. The SAFEs are classified as mezzanine equity due to the terms of the cash-redemption features and appear on the balance sheet under the caption, "Simple agreement for future equity". The issuance costs for SAFEs are included in "Additional paid-in capital" on the balance sheet.

NOTE 10 – WARRANTS

The following summarizes the Company's warrant activity for all prior years:

Year Issued	Warrants Issued	Strike Price
2013	90,000	$ 1.25
2014	60,000	1.25
2015	60,000	1.25
2016	160,000	1.25
2017	10,000	1.25
2017	80,000	2.00
2019	80,000	2.00
Total number of warrants and average strike price	540,000	$ 1.47

On January 6, 2020, the Board of Directors approved reissuing the existing 540,000 warrants at a strike price of $0.10 and 7-year term. The fair valued of the reissued warrants was estimated at $1,079,985 on the issuance date.

The warrants' fair value was estimated using the Black Scholes Option Pricing Model with following assumptions:

	January 1, 2020
Weighted average fair value per unit when issued	0.20
Risk-free interest rate	1.79%
Dividend yield	-
Expected term	7 years
Volatility	300%

In December 2021, all outstanding warrants were exercised at the $0.10 strike price for a total of $54,000. No additional warrants were issued in 2022 or 2021.

NOTE 11 – COMMITMENTS AND CONTINGENCIES

Contractual Agreements

On January 1, 2016, the Company entered into an independent contractor agreement with the Company's President for an annual fee of $96,180. On September 13, 2022, the Company terminated the independent contractor agreement and replaced it with an employment agreement which includes a cash and non-cash compensation component, certain benefits, and eligibility for a bonus beginning in 2023. (see Note 4, Accrued Liabilities, Related Party and Note 13, Related Party Transactions).

On March 17, 2018, the Company entered into independent contractor agreements with its former Chief Financial Officer for an annual fee of $48,000 without any benefits. The agreement also provided for certain cash and equity compensations payable for any merger, acquisition, or joint economic undertaking introduced by the former Chief Financial Officer within twelve months after termination. The Company does not consider such an event to be probable and, accordingly, no liability has been recognized in the financial statements.

The Company also entered into an employment agreement with the current Chief Financial Officer on January 23, 2023 which includes a cash and non-cash compensation component, certain benefits, and eligibility for a bonus beginning in 2023.

License Agreement

On December 15, 2014, the Company entered into an exclusive license agreement to in-license a patent family from The Board of Trustees of the University of Arkansas ("University"). The University assigned its rights and obligations under the agreement to BioVentures, LLC. The agreement grants the Company certain exclusive rights to develop and commercialize products that rely on the patents in exchange for the Company paying patent related expenses, an annual continuation fee of $2,500 and certain other non-cash compensation. In addition, the Company is required to pay a royalty for any products relying on the patents that are commercialized or licensed to other parties. As of December 31, 2022 and 2021, the Company was current on all obligations required by the agreement.

NOTE 12 – INTELLECTUAL PROPERTY AND PATENTS

The Company's product candidate, SQX770, has patent protection under a group of U.S. and foreign patents. The formulation of the drug and its use to prevent cold sores was originally invented jointly by Dr. McTavish, who assigned his interest to the Company, and Dr. Thomas Horn and Dr. Sandra Johnson, whose interests are exclusively licensed to the Company (see Note 11, Commitments and Contingencies). This invention is the basis for two U.S. patents that gave the Company its initial patent protection. One of the patents has claims directed to a method of treating either genital or oral herpes by applying SADBE or similar contact sensitizers to a herpes lesion. The other patent has claims directed to a pharmaceutical composition comprising SADBE dissolved in DMSO, which covers the SQX770 formulation as a composition of matter.

Dr. McTavish is also the sole inventor of two other U.S. patents which the Company exclusively owns. These patents have claims directed to a method of treating either genital or oral herpes by applying SADBE or similar contact sensitizers topically to a site other than to a herpes lesion. The Company also has a U.S. patent pending for the use of SADBE or similar compounds to treat molluscum contagiosum, a common contagious viral skin disease. A U.S. patent application has also been submitted for claims directed to kits and delivery devices that will be used for the commercial products that are sold with the SQX770 drug formulation.

The foregoing patents have various expiration dates ranging from 2028 to 2036. The pending patent applications have expiration dates later than 2036. In addition, these dates may be extended for the time spent in the FDA approval process. The Company has also similar patents in several of the key foreign markets. It is expected that other patent applications will be filed to cover the Squarex products and methods of medical treatment using those products as the Company continues in its clinical trials.

NOTE 13 – RELATED PARTY TRANSACTIONS

Outstanding balances with related parties are summarized in the following table:

	As of December 31,	Year Ended December 31,

	2022	2021	2022	2021
Accounts payable, related party	$ 12,070	$ 441	$ 19,676	$ 44,102
Line of credit - principal	488,509	445,794	42,715	159,793
Line of credit - interest	163,000	74,007	88,993	52,957
Line of credit - total	651,509	519,801	131,708	212,750
Executive management fees	283,731	216,405	67,326	96,180
Executive management salary	28,854	-	28,854	-
Director service fees	30,000	30,000	-	11,250
Rent	12,698	12,698	-	15,656
Accrued liabilities, related party	355,283	259,103	96,180	123,086
Total transactions, related party	$ 1,018,862	$ 779,345	$ 247,564	$ 379,938

Accounts payable, related party

The Company contracts with a law firm in which Dr. McTavish is the owner where he performs patent related services in securing and defending intellectual property rights. The Company believes that the terms are commercially reasonable and fees generally representative of the market value for similar services, and accordingly, the Company expects to continue engaging legal services with Dr. McTavish in the future. Patent legal fees are recorded on the balance sheet in "Accounts payable, related party" and expensed in "Research and development" on the statement of operations.

Line of credit - principal and interest

The Company funds its current operating expenses by drawing down on a Line of Credit (see Note 6, Line of Credit, Related Party). provided by Dr. McTavish, who is a related party. The Line of Credit has a 15% per annum interest rate with principal and interest due by December 31, 2024. Interest is accrued in "Accrued interest, related party" on the balance sheet and expensed in "Interest expense – related party, net" on the statement of operations. The principal balance is recorded in "Line of credit, related party" on the balance sheet.

Executive management - contractor fees and salary

In October 2019, the Company contracted with Dr. McTavish, who is a related party, to function as the Company's President and to conduct, coordinate and supervise the Company's activities to exploitation of pharmaceutical compositions. The Company accrued a monthly expense of $8,015 for Dr. McTavish services which was recorded as a contractor fee until September 13, 2022 when Dr. McTavish became an employee and after that time his monthly expense was recorded as salary. During the last ten months of 2022, the Company repaid part of the Line of Credit by an amount equal to the $8,015 expense which was accrued each month (see Note 6, Line of Credit, Related Party and Note 11, Commitments and Contingencies). The monthly expense is accrued in "Accrued liabilities, related party" on the balance sheet and expensed in "General administrative" on the statement of operations.

Director service fees

From 2019 to 2021, the Company engaged the services of one of the Board of Directors, who is considered a related party. In exchange for these services, the Company accrued a monthly expense of $1,250. The monthly expense is accrued in "Accrued liabilities, related party" on the balance sheet and expensed in "General administrative" on the statement of operations. Board of Directors fees for serving on the Board of Directors and its committees have not been accrued for in 2021 and 2022, as these fees first commence in 2023.

Office Lease

As of June 1, 2020, the Company entered into a one-year sublease agreement with IGF, a company controlled by a related party, for the use of the Lab. The Company elected to use the short-term lease exception and recognized the rental expense for the sublease in the statement of operations in 2021 and 2020. The sublease agreement was terminated in 2021.

NOTE 14 – INCOME TAXES

Prior to the Company's conversion to a corporation on September 13, 2022, the Company elected to be treated as a pass-through entity for income tax purposes. Accordingly, taxable income and losses of the Company were reported on the income tax returns of its members, and no provision for federal income taxes has been recorded in the accompanying financial statements for any periods prior to September 13, 2022. If the Company had been a taxable entity prior to the conversion date, the Company would not have recorded a provision for income taxes as the Company has sustained losses since its inception.

No income tax benefit has been recognized for the net operating losses that were incurred since Company's conversion to a corporation for the year ending December 31, 2022. Instead, a valuation allowance has been recorded that recognizes that it is more likely than not that the deferred tax assets will not be realized due to its uncertainty.

The income tax provision for the years ended December 31, 2022 and 2021 consists of the following:

	Year Ended December 31,	
	2022	**2021**
Federal		
Current	$ -	$ -
Deferred	-	-
State and local		
Current	-	-
Deferred	-	-
Total provision for income taxes	$ -	$ -

A reconciliation of the Company's statutory tax rate to the effective rate is as follows:

	Year Ended December 31,	
	2022	**2021**
Federal statutory rate	21%	21%
State income taxes, net of federal tax benefit	8	8
Permanent differences	-	-
Other differences	-	-
Losses passed through to members (prior to incorporation) and change in valuation allowance (after incorporation)	(29)	(29)
Effective tax rate	-%	-%

The components of the Company's provision for deferred taxes are as follows:

	As of December 31,	
	2022	**2021**
Deferred Tax Assets:		
Net operating loss carryforwards	$ 64,192	$ -
Capitalized research and development costs	5,178	-

Other deferred tax assets	1,059	-
Deferred tax assets	70,429	-
Deferred Tax Liabilities:		
Deferred tax liabilities	(3,416)	-
Deferred tax assets, net	67,013	-
Less: valuation allowance	(67,013)	-
Deferred tax provision	$ -	$ -

On December 22, 2017, the U.S. government enacted the Tax Cuts and Jobs Act ("Tax Act"). The Tax Act significantly revises U.S. tax law by, among other provisions, lowering the U.S. federal statutory income tax rate to 21 percent. Beginning in 2022, the Tax Act eliminated the right to deduct research and development expenditures for tax purposes in the period the expenses were incurred and instead requires for research and development expenditures incurred in the U.S. to be amortized over five tax years.

NOTE 15 – SUBSEQUENT EVENTS

In January 2023, the Company granted 160,000 options collectively to the four independent directors. In January, the Company also granted 100,000 options to Dr McTavish under the terms of his employment agreement as President and Chief Executive Officer and 150,000 options to Mr. Kardaras under the terms of his employment agreement as Chief Financial Officer. These options have a vesting schedule of one-third vesting immediately and the remaining two-thirds over a 3-year period.