PRIVATE PLACEMENT MEMORANDUM

TRANSCODE THERAPEUTICS, INC.

6 Liberty Square #2382 Boston MA 02109

www.transcodetherapeutics.com

UP TO 9,000,000 SHARES

SERIES A PREFERRED STOCK

| | Price Per Share | Shares Offered | Proceeds to Issuer* |
|---------|-----------------|----------------|---------------------|
| Minimum | \$4.00 | 3,750,000 | \$15,000,000 |
| Maximum | \$4.00 | 9,000,000 | \$36,000,000 |

* Before expenses of the offering

In this Private Placement Memorandum, or PPM, the term "TransCode Therapeutics," "TransCode," "we," "us," "our," or the "Company" refers to TransCode Therapeutics, Inc.

All of the securities offered are being sold for TransCode's own account. There is no public market for our securities nor do we expect that there will be one in the near future, if ever.

An investment in our securities involves a high degree of risk. In making an investment decision, you must rely on your own examination of us and the terms of the offering, including the merits and risks involved. You should only invest in these securities if you can afford a complete loss of your investment. You should read the complete discussion of the risk factors set forth in this PPM.

Neither the U.S. Securities and Exchange Commission, or SEC, nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this PPM. Any representation to the contrary is a criminal offense.

NOTICES TO INVESTORS

THE SECURITIES OFFERED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES ACT, OR THE SECURITIES LAWS OF ANY STATE AND ARE BEING OFFERED AND SOLD IN RELIANCE ON EXEMPTIONS FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT SET FORTH IN SECTION 4(A)(2) THEREOF AND RULE 506 OF REGULATION D PROMULGATED THEREUNDER, OR REGULATION D. WE HAVE ELECTED TO SELL SECURITIES ONLY TO ACCREDITED INVESTORS AS SUCH TERM IS DEFINED IN RULE 501(A) OF REGULATION D. EACH PROSPECTIVE INVESTOR WILL BE REQUIRED TO MAKE REPRESENTATIONS AS TO THE BASIS UPON WHICH SUCH INVESTOR QUALIFIES AS AN ACCREDITED INVESTOR; INDEPENDENT VERIFICATION OF SUCH STATUS WILL BE REQUIRED PURSUANT TO RULE 506(c) OF REGULATION D. SEE "PLAN OF DISTRIBUTION."

THE SECURITIES OFFERED HEREBY WILL BE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER THE SECURITIES ACT AND UNDER APPLICABLE STATE SECURITIES LAWS OR PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. INVESTORS SHOULD BE AWARE THAT THEY MAY BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME. ONLY PERSONS WHO CAN AFFORD TO LOSE THEIR ENTIRE INVESTMENT IN THE SHARES SHOULD PURCHASE THE SHARES.

THE INFORMATION PRESENTED HEREIN WAS PREPARED AND SUPPLIED SOLELY BY TRANSCODE THERAPEUTICS, INC. AND IS BEING FURNISHED SOLELY FOR USE BY PROSPECTIVE INVESTORS IN THIS OFFERING (THE "OFFERING"). WE MAKE NO REPRESENTATIONS AS TO OUR FUTURE PERFORMANCE OR THE VALUE OF OUR SECURITIES.

WE MAY WITHDRAW, CANCEL, OR MODIFY THIS OFFERING AT ANY TIME AND WITHOUT NOTICE. WE RESERVE THE RIGHT IN OUR SOLE DISCRETION TO REJECT ANY SUBSCRIPTION IN WHOLE OR IN PART NOTWITHSTANDING TENDER OF PAYMENT, OR TO ALLOT TO ANY PROSPECTIVE INVESTOR LESS THAN THE NUMBER OF SECURITIES SUBSCRIBED FOR BY SUCH INVESTOR.

THIS PPM DOES NOT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF ANY OFFER TO BUY ANY SECURITY OTHER THAN THE SECURITIES OFFERED HEREBY, NOR DOES IT CONSTITUTE AN OFFER TO SELL OR A SOLICITATION OF ANY OFFER TO BUY SUCH SECURITIES BY ANYONE IN ANY JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS NOT AUTHORIZED, OR IN WHICH THE PERSON MAKING SUCH OFFER OR SOLICITATION IS NOT QUALIFIED TO DO SO. NEITHER THE DELIVERY OF THIS PPM NOR ANY SALE MADE HEREUNDER SHALL, UNDER ANY CIRCUMSTANCES, CREATE ANY IMPLICATION THAT THERE HAS BEEN NO CHANGE IN OUR AFFAIRS SINCE THE DATE HEREOF. THIS PPM CONTAINS SUMMARIES OF CERTAIN PERTINENT DOCUMENTS, AND APPLICABLE LAWS AND REGULATIONS. SUCH SUMMARIES ARE NOT COMPLETE AND ARE QUALIFIED IN THEIR ENTIRETY BY REFERENCE TO THE COMPLETE TEXTS OF THE RELATED DOCUMENTS, LAWS AND REGULATIONS.

PROSPECTIVE INVESTORS ARE NOT TO CONSTRUE THE CONTENTS OF THIS PPM AS LEGAL, INVESTMENT OR TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT HIS OR HER OWN COUNSEL, ACCOUNTANT AND OTHER ADVISORS AS TO LEGAL, INVESTMENT, TAX AND RELATED MATTERS PRIOR TO PURCHASING ANY SECURITIES.

WE MAKE NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, AS TO THE ACCURACY OR COMPLETENESS OF THE INFORMATION IN THIS PPM OR IN ANY ADDITIONAL EVALUATION MATERIAL, WHETHER WRITTEN OR ORAL, MADE AVAILABLE IN CONNECTION WITH ANY FURTHER INVESTIGATION OF US. WE EXPRESSLY DISCLAIM ANY AND ALL LIABILITY THAT MAY BE BASED UPON SUCH INFORMATION, ERRORS THEREIN OR OMISSIONS THEREFROM. ONLY REPRESENTATIONS AND WARRANTIES, IF ANY, WHICH WE MAKE IN A DEFINITIVE WRITTEN AGREEMENT REGARDING A TRANSACTION WE ENTER INTO WITH AN INVESTOR, WHEN, AS AND IF EXECUTED, AND SUBJECT TO SUCH LIMITATIONS AND RESTRICTIONS AS MAY BE SPECIFIED THEREIN, WILL HAVE ANY LEGAL EFFECT. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED TO THE CONTRARY IN WRITING, THIS PPM SPEAKS AS OF THE DATE HEREOF.

NO PERSON HAS BEEN AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATIONS IN CONNECTION WITH THIS OFFERING OTHER THAN THOSE CONTAINED IN THIS PPM, AND, IF GIVEN OR MADE, MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY US. WE HAVE NOT RETAINED ANY INDEPENDENT PROFESSIONALS TO COMMENT ON OR OTHERWISE PROTECT THE INTERESTS OF POTENTIAL INVESTORS. ALTHOUGH WE HAVE RETAINED OUR OWN COUNSEL, NEITHER SUCH COUNSEL NOR ANY OTHER INDEPENDENT PROFESSIONALS HAVE MADE ANY EXAMINATION OF ANY FACTUAL MATTERS HEREIN, AND POTENTIAL INVESTORS SHOULD NOT RELY ON OUR COUNSEL REGARDING ANY MATTERS HEREIN DESCRIBED.

THERE IS NO MARKET FOR OUR SECURITIES AND THERE IS NO ASSURANCE THAT A PUBLIC TRADING MARKET WILL EVER BE ESTABLISHED. PURCHASERS OF THE SECURITIES ARE NOT BEING GRANTED ANY REGISTRATION RIGHTS. A PURCHASE OF THE SECURITIES SHOULD BE CONSIDERED AN ILLIQUID INVESTMENT.

THIS PPM IS SUBJECT TO AMENDMENT AND SUPPLEMENTATION AS APPROPRIATE. WE DO NOT INTEND TO UPDATE THE INFORMATION CONTAINED IN THE PPM FOR ANY INVESTOR WHO HAS ALREADY MADE AN INVESTMENT. WE MAY UPDATE THE INFORMATION CONTAINED HEREIN FROM TIME TO TIME AND PROVIDE SUCH UPDATED DOCUMENT TO POTENTIAL INVESTORS, BUT WE UNDERTAKE NO OBLIGATION TO PROVIDE SUCH UPDATED DOCUMENTS TO ANY INVESTOR WHO HAS ALREADY MADE HIS OR HER INVESTMENT.

A COPY OF THIS PPM AND THE SUBSCRIPTION AGREEMENT TO BE COMPLETED BY INVESTORS WISHING TO SUBSCRIBE TO PURCHASE OUR SECURITIES SHALL BE DELIVERED TO EVERY PERSON SOLICITED TO BUY ANY OF THE SECURITIES HEREBY OFFERED, AT THE TIME OF THE INITIAL OFFER TO SELL.

NOTICE TO RESIDENTS OF ALL U.S. STATES

THE SHARES OFFERED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT, OR THE SECURITIES LAWS OF ANY STATES OR OTHER JURISDICTIONS AND ARE BEING OFFERED AND SOLD IN RELIANCE ON EXEMPTIONS FROM REGISTRATION REQUIREMENTS UNDER THE SECURITIES ACT AND SUCH LAWS, INCLUDING, WITHOUT LIMITATION, RULE 506 OF REGULATION D. THE SHARES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION, ANY STATE SECURITIES COMMISSION OR ANY OTHER REGULATORY AUTHORITY, NOR HAVE ANY OF THE FOREGOING AUTHORITIES PASSED UPON OR ENDORSED THE MERITS OF THIS OFFERING OR THE ACCURACY OR ADEQUACY OF THIS PPM. ANY REPRESENTATION TO THE CONTRARY IS UNLAWFUL.

NOTICE TO ALL NON-U.S. INVESTORS GENERALLY

THE DISTRIBUTION OF THIS PPM AND THE OFFER AND SALE OF SHARES IN CERTAIN JURISDICTIONS OUTSIDE THE UNITED STATES MAY BE RESTRICTED BY LAW.

THE SECURITIES OFFERED HEREIN HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT IN RELIANCE UPON REGULATION S AND, FOR A PERIOD OF AT LEAST ONE YEAR FROM THE CLOSING OF THIS OFFERING, MAY NOT BE OFFERED OR SOLD IN THE UNITED STATES OR TO U.S. PERSONS (OTHER THAN DISTRIBUTORS) UNLESS THE SECURITIES ARE REGISTERED UNDER THE SECURITIES ACT, OR ANY EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT IS AVAILABLE. IN ADDITION, HEDGING TRANSACTIONS INVOLVING OUR SHARES MAY NOT BE CONDUCTED UNLESS IN COMPLIANCE WITH THE SECURITIES ACT.

THIS MEMORANDUM DOES NOT CONSTITUTE AN OFFER TO SELL OR THE SOLICITATION OF AN OFFER TO BUY OUR SECURITIES IN ANY JURISDICTION TO ANY PERSON TO WHOM IT IS UNLAWFUL TO MAKE SUCH OFFER OR SOLICITATION IN SUCH JURISDICTION. PROSPECTIVE NON-U.S. INVESTORS SHOULD INFORM THEMSELVES AS TO THE LEGAL REQUIREMENTS AND TAX CONSEQUENCES WITHIN THE COUNTRIES OF THEIR CITIZENSHIP, RESIDENCE, DOMICILE AND PLACE OF BUSINESS WITH RESPECT TO THE ACQUISITION,

HOLDING OR DISPOSAL OF SHARES, AND ANY FOREIGN EXCHANGE RESTRICTIONS THAT MAY BE RELEVANT THERETO.

TAXES

Prospective investors are not to construe the contents of this PPM as legal, financial or tax advice. The tax aspects of an investment in our securities require careful and informed study with respect to an investor's personal tax and financial position. Accordingly, no person should invest in our securities without first obtaining independent expert advice as to the tax effects of an investment in our securities. Each prospective investor should consult his or her own counsel, accountant and other advisors as to legal, tax and related matters prior to purchasing our securities.

FORWARD-LOOKING STATEMENTS

Our PPM may contain forward-looking statements relating to, among other things, our company, our business plan and strategy, and our industry. When used in our offering materials, the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "project," "should," and similar expressions are intended to identify forward-looking statements. Forward-looking statements are based on our beliefs, assumptions, and information currently available to us and reflect our current views with respect to future events. Forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from those contained in or suggested by the forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they are made. We do not undertake any obligation to revise or update these forward-looking statements to reflect events or circumstances after such date or to reflect the occurrence of unanticipated events.

GLOSSARY OF TERMS

A Glossary of Terms used in this PPM is included at Exhibit A.

Table of Contents

| NOTICES TO INVESTORS | 2 |
|---|-------------|
| Notice to Residents of All LLS States | 2 |
| Notice to All Non-LLS. Investors Generally | 4 |
| TAXES | |
| Forward-Looking Statements | 5 |
| GLOSSARY OF TERMS | 5 |
| SUMMARY | 9 |
| Company | 9 |
| Technology | وو م |
| Selected Risks Associated With Our Business | 0 |
| | 10 |
| | 12 |
| DILITION | 14 |
| BUSINESS | 17 |
| Overview | 17 |
| Market Overview | 17 |
| PRODUCT-CANDIDATES | 19 |
| lead therapeutic-candidate TTX-MC138 | 19 |
| Therapeutic concent | 19 19 |
| Potential advantages of TTX-MC138: | 10 |
| Stage II /III Metastatic Triple-Negative Breast Cancer, Mouse Model | 20 |
| Stage IV Metastatic Triple-Negative Breast Cancer, Mouse Model | 21 |
| | 21 |
| Proposed clinical proof of concept | 22 |
| Single tumor type clinical trial | 22 |
| Adaptive design clinical trial | 23 23 |
| Proposed Phase IIa Trial Criteria (to be determined) | 23 |
| Predictive Biomarker | 23 |
| Potential Litility of Riomarker Test | 24 |
| | 23 |
| Theraneutic Delivery system | 20 |
| Intellectual Property | 20 28 |
| Datents | 28 |
| Research and Development | 28 |
| | 20 20 |
| | 20 |
| Biognalytical | 3030 |
| Dioanalytical | 3030 |
| | 3030 |
| Regulatory | 30 |
| Chemistry Manufacturing and Controls (CMC) | 31 21 |
| Development Plan Timeline | 31 |
| Milestones | 31 |
| | 32 |
| Clinical and Preclinical Trials | 33 |
| The FDA Approval Process | 33 |
| Ongoing Regulatory Requirements | 35 |
| Third-party Regulatory Requirements | טכ דכ |
| Additional Regulatory Requirements | 3/ วง |
| Auditional Regulatory Reguliences | ۵۵ ۵۵ |
| Suppliers | |
| בוווטטלכט | 39 |

| Litigation | 39 |
|---|--------|
| Property | 39 |
| MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS | 42 |
| Results of operations | 42 |
| Liquidity and capital resources | 42 |
| DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES | 44 |
| COMPENSATION OF DIRECTORS AND EXECUTIVE OFFICERS | 48 |
| SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN SECURITYHOLDERS | 48 |
| Restricted Stock | 49 |
| Treasury Stock | 49 |
| DESCRIPTION OF CONVERTIBLE NOTES PAYABLE | 49 |
| DESCRIPTION OF CAPITAL STOCK | 50 |
| General | 50 |
| Board of Directors | 50 |
| Capital Stock | 50 |
| Preferred Stock | 50 |
| Dividends | 50 |
| Liquidation Preference | 51 |
| Voting Rights | 51 |
| Conversion | 51 |
| Restrictions On Transferability | 51 |
| Protective Provisions | 52 |
| Common Stock | 52 |
| Dividend Rights | 52 |
| Voting Rights | 52 |
| Right to Receive Liquidation Distributions | 52 |
| Rights and Preferences | 52 |
| Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws | 53 |
| Section 203 of the Delaware General Corporation Law | 53 |
| Certificate of Incorporation and Bylaws | 54 |
| Potential Effects of Authorized but Unissued Stock | 54 |
| PLAN OF DISTRIBUTION | 55 |
| Foreign Regulatory Action | 55 |
| Procedure for Subscribing | 56 |
| Escrow Agent | 57 |
| INVESTOR SUITABILITY STANDARDS | 57 |
| General | 57 |
| Suitability Requirements | |
| Federal income tax consequences | 61 |
| EXPERTS | 61 |
| RISK FACTORS | 62 |
| Risks Related to Our Business and Industry | 62 |
| Risks Related to Third Parties and Suppliers | 68 |
| Regulatory Risks | 73 |
| Risks Related to Government Regulation | 75 |
| Risks Related to Other Government Regulations | 76 |
| Risks Related to Market Conditions | 78 |
| Adverse market and economic conditions may exacerbate certain risks affecting our business. | 79 |
| Risks Related to Intellectual Property | 79 |
| Risks Related to the Offering | 82 |
| Risks Related to Control by Certain Shareholders/Acquisition | 85 |
| Risks Related to Financial Reporting | 85 |
| Risks Related to Dividends and Carryforwards | 87 |
| • | |

| Risks Related to Our Facilities | 88 |
|--|----|
| WHERE YOU CAN OBTAIN MORE INFORMATION | 88 |
| EXHIBIT A – GLOSSARY OF TERMS | 90 |
| EXHIBIT B – FORM OF SUBSCRIPTION AGREEMENT | 99 |
| EXHIBIT C – FORM OF CERTIFICATE OF INCORPORATION | 99 |
| AND BYLAWS | 99 |
| EXHIBIT D – AUDITED FINANCIAL STATEMENTS | 99 |

SUMMARY

COMPANY

TransCode Therapeutics, Inc. is a Boston-based, pre-clinical biopharmaceutical company incorporated in the State of Delaware on January 11, 2016. We are focused on the discovery, development and commercialization of a pipeline of innovative microRNA targeted therapeutics for treating cancer, with an initial focus on metastasis. We have developed what we believe will be, if approved, better cancer treatments delivered with a better delivery mechanism. There is no guarantee that any of our technologies will prove safe or effective in humans.

TECHNOLOGY

Virtually all cancers, including cancers of the blood and the lymphatic system (leukemia, multiple myeloma, and lymphoma), can form metastatic tumors. Metastatic tumors are tumors that have spread from the area where the cancer started to other areas of the body. The most common metastatic tumors are tumors in the lymph nodes, bones, liver, and lungs. Considering that approximately 9 out of 10 cancer deaths are due to metastasis and not primary tumors, we believe that there is a significant potential market for our therapeutics, if approved.

Our lead therapeutic-candidate, TTX-MC138, developed by our scientific co-founders to treat metastasis, has achieved pre-clinical proof of concept in animal models of metastatic breast cancer and in the lab *in vitro*. Animals treated with TTX-MC138 demonstrated complete regression of established metastases and lifetime remission after four to six weekly injections. Results in animals often do not correlate with results in humans. The technology underlying TTX-MC138 was developed primarily at Massachusetts General Hospital, or MGH, in Boston, largely through grants from the National Institutes of Health totaling nearly \$5.3 million since 2012. The recipients of these grants were acting in their capacity as researchers at MGH and were not directly working for TransCode. In 2018, we secured an exclusive worldwide license for this technology from MGH.

TTX-MC138 has been designed to specifically inhibit/inactivate microRNA-10b, a driver/master regulator of metastatic cell viability, migration and invasion. Our animal testing showed that inhibition of microRNA-10b by TTX-MC138, combined with a low-dose cytostatic (doxorubicin) at metastatic sites, led to the death of metastatic cells and elimination of established metastases after four to six weekly treatments. There was no evidence of recurrence for the lifetime of the animals and no systemic toxicity. These studies are the basis for our primary initial clinical indication: elimination/regression of established metastases in stage II-IV metastatic breast cancer.

The choice of microRNA-10b as a target is supported by its potentially broad relevance to other forms of cancer. Over 400 studies published in the literature to date have demonstrated that the influence of microRNA-10b extends beyond breast cancer to pancreatic, lung, colorectal, gastric, bladder, ovarian, and hepatocellular cancers among others, suggesting that our approach may be broadly applicable to metastatic disease. We intend to also explore these other indications.

SELECTED RISKS ASSOCIATED WITH OUR BUSINESS

An investment in our securities involves substantial risks and uncertainties, including those that are generally associated with small, early-stage companies operating in the biopharmaceutical industry. The future outcome of these risks and uncertainties may materially and adversely affect our ability to develop and commercialize our technologies, our business, our financial condition, our results of operations, our cash flows, and the value of our securities. Before investing in our securities, you should fully read our PPM and carefully consider the risks and uncertainties described in this PPM, including those described in Risk Factors. Any of the factors set forth in Risk Factors may limit our ability to achieve our objectives. There may be other factors of which we are not aware, and which therefore are not included in Risk Factors, that also may adversely affect us and the value of our securities. You should only invest in our securities if you are able to sustain a complete loss of your investment.

A summary of some of the principal risks includes:

- We are an early-stage, pre-clinical company with no approved products; this makes assessment of our future viability difficult to evaluate.
- We need the funds from the offering to strengthen our financial condition. We expect to need additional funds.
- We have a limited history, have incurred losses since inception, and expect to continue to incur substantial losses for the foreseeable future. We may never achieve profitability or sustain it if achieved.
- Even after completion of this offering, we may need additional funds in the future.
- *Preparing financial projections and forecasts involves uncertainties and contingencies.*
- Because our product-candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenues.
- Our business is highly dependent on the success of TTX-MC138, currently our only advanced therapeutic product-candidate, which is at the early stages of development.
- We are early in our development efforts. TTX-MC138 is in pre-clinical development and has yet to be tested in humans. If we are unable to successfully move to clinical development and develop and commercialize TTX-MC138 or other product-candidates, or we experience significant delays in doing so, our business will be materially harmed.
- If clinical trials of TTX-MC138 fail to demonstrate safety and efficacy, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TTX-MC138.
- If we fail to obtain needed capital, we may be unable to complete development and commercialization of TTX-MC138.
- Our securities are not registered with any government authority or trading system.

You are urged to read all the risk factors at "Risk Factors" in this PPM.

THE OFFERING

We are offering to accredited investors up to 9,000,000 shares of our Series A Preferred Stock ("Series A Preferred") on a "best efforts" basis (the "offering"). We seek to raise up to \$36 million in this Offering although we will accept a minimum of \$15.0 million. We expect the offering period will continue from the date of this PPM until the earlier of (i) the date upon which \$36 million (or the minimum offering) of Series A Preferred has been sold or (ii) April 30, 2019, but we may extend the offering period or terminate it earlier at our sole discretion.

The minimum subscription is \$500,000; however, we reserve the right in our sole discretion to accept subscriptions for lesser amounts. Our officers, directors, employees, and advisors may participate in the Offering.

The shares of Series A Preferred to be issued in the offering include shares issuable on conversion of the principal and accrued interest due on convertible promissory notes. The principal and accrued interest on convertible promissory notes will be included in determining whether the minimum offering has been achieved. Pending completion of the minimum offering, subscriptions will be held in escrow. In the event the minimum offering is not achieved by the end of the offering period, subscriptions will be returned to investors without interest and without any deductions.

We may hold one or more closings at any time after the minimum offering has been achieved and after other applicable conditions have been satisfied or waived.

Accredited investors wishing to purchase our securities must complete a subscription agreement in the form attached to this PPM as Exhibit B. Subscriptions are payable via check, wire transfer, or electronic funds transfer via Automated Clearing House or ACH as specified in the subscription agreement. Subscriptions are subject to acceptance by us at our sole discretion. We need not accept subscriptions in the order received. If we reject a subscription in whole or in part, the subscription funds representing the portion rejected will be promptly returned without interest and without any deductions.

| | Shares of Common Stock | |
|-----------------------------|------------------------|----------------|
| (assuming full conversion) | <u>Minimum</u> | <u>Maximum</u> |
| Outstanding Before Offering | 7,643,500 | 7,643,500 |
| Securities Offered | 3,750,000 | 9,000,000 |
| Outstanding After Offering | 11,393,500 | 16,643,500 |

* Excludes shares issuable pursuant to an equity incentive plan we intend to adopt.

The offer and sale of our securities is intended to be exempt from the registration requirements of the Securities Act pursuant to Rule 506(c) of Regulation D promulgated thereunder and is intended to be exempt from the registration requirements of applicable state securities laws. We

are offering our Series A Preferred solely to accredited investors as such term is defined in Rule 501(a) of Regulation D of the Securities Act who also meet certain other suitability standards (see "Investor Suitability Standards"). To support our qualification for the exemption from registration requirements, independent verification of each subscriber's status as an accredited investor will be required. Each investor will be required to represent in writing that he, she or it qualifies as an accredited investor and must demonstrate the basis for such qualification. The fact that an accredited investor meets the suitability requirements does not necessarily mean that an investment in our securities is suitable for that investor. Each prospective investor should consult with his or her own investment, legal, tax and other professional advisors before investing in our securities.

USE OF PROCEEDS

All the net proceeds from this offering will be for our account; no shares are offered by existing shareholders. The net proceeds from the offering will be used primarily for testing, research and manufacturing necessary to prepare for clinical trials, and, depending on the amount of net proceeds, possibly for expenses related to clinical trials, with any remaining proceeds used for working capital and general corporate purposes. The table below illustrates the net proceeds from the minimum and maximum amounts of securities sold. This table also shows our planned application of the net proceeds. The number of shares sold, and thus, the amount of net proceeds, may differ from the levels assumed in this table, and there is no assurance that the net proceeds will be applied as indicated below.

| Series A Preferred Shares Sold | 3,750,000 | 9,000,000 | |
|---------------------------------------|------------------------|------------------------|--|
| Price Per Share | \$4.00 | \$4.00 | |
| Amount Raised | \$15,000,000 | \$36,000,000 | |
| Estimated Offering Expenses | \$1,450,000 | \$2,920,000 | |
| Estimated Net Proceeds | \$13,550,000 | \$33,080,000 | |
| Planned Application of Funds | | | |
| IND Enabling Studies | \$1,065,000 | \$1,065,000 | |
| Manufacturing | \$3,597,775 | \$5,330,175 | |
| Clinical Testing | \$3,000,000 | \$18,000,000 | |
| Patent and Licensing Expenses | \$422,578 | \$822,578 | |
| Research and Development | \$8,085,353 | \$25,217,753 | |
| Corporate and Administrative Expenses | \$2,732,883 | \$5,080,505 | |
| Total Planned Expenditures | \$10,818,236 | \$30,298,258 | |
| Addition to Working Capital | \$2,731,764 | \$2,781,742 | |
| Significant Milestones Targeted | File IND, enroll 20 | Complete Phase IIa | |
| (there is no assurance that any | patients in clinical | Adaptive Design trial | |
| milestone will be achieved) | trial; establish Proof | in 120 patients with | |
| | of Principle; | multiple cancer types; | |
| | establish Proof of | file NDA seeking | |
| | Concept in up to 20 | FDA approval of | |
| | patients | therapeutic for | |
| | | patients with | |
| | | metastatic cancer | |

Pending use of the estimated net proceeds from this offering, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities, certificates of deposit or government securities. There is no assurance that whatever net proceeds are received will be sufficient for the intended purposes set out in the table above and elsewhere in this PPM. We reserve the right to change the use of proceeds if our management believes it is in the best interests of the Company.

DILUTION

If you invest in our Series A Preferred, and assuming your Series A Preferred are converted into our common stock, you will experience dilution to the extent of the difference between the price per share of our Series A Preferred that you pay in this offering and the pro forma net tangible book value per share of our common stock after the offering.

Net tangible book value per share is determined by dividing (1) our total tangible assets less our total liabilities by (2) the number of shares of common stock outstanding. Our historical net tangible book value at September 30, 2018, was negative \$187,509, or negative \$0.03 per share, based on 7,643,500 shares of common stock outstanding at December 31, 2018. Our pro forma net tangible book value based on these data, assuming all shares of Series A Preferred sold in this offering convert into common stock, is set forth in the following table:

| | <u>Minimum</u> | <u>Maximum</u> |
|---|---------------------|--------------------|
| Net Tangible Book Value (Deficit) Before Offering | (\$187,509) | (\$187,509) |
| Common Shares Outstanding Before Offering | 7,643,500 | 7,643,500 |
| Net Tangible Book Value (Deficit) per Share before Offering | (\$0.025) | (\$0.025) |
| Offering Drive new Share | ¢4.00 | \$4.00 |
| Offering Price per Share | \$4.00 | \$4.00 |
| Assumed Shares Sold in Offering | 3,750,000 | 9,000,000 |
| Increase in Net Tangible Book Value Attributable to Shares | | |
| Sold in Offering (After Offering Expenses) | \$13,550,000 | \$33,080,000 |
| | <i>+ 10,000,000</i> | <i>400,000,000</i> |
| Increase in Net Tangible Book Value per Share Attributable | | |
| to Shares Sold in Offering | \$3.61 | \$3.68 |
| Pro Forma Nat Tangible Pools Value After Offering | \$12 262 401 | \$22 802 401 |
| Pio Forma Net Tangiole Book Value After Offerning | \$15,502,491 | \$52,892,491 |
| Pro Forma Common Shares Outstanding After Offering | 11,393,500 | 16,643,500 |
| Net Tangible Book Value per Share After Offering | \$1.17 | \$1.98 |
| | Ψ1.17 | φ1.96 |
| Dilution of Net Tangible Book Value per Share to Purchasers | | |
| in this Offering | \$2.83 | \$2.02 |
| | 42 .03 | ····· |
| Increase in Net Tangible Book Value per Share to | | |
| Shareholders Before Offering* | \$1.20 | \$2.00 |
| | + • | |

* may not add precisely due to rounding

The following table sets forth, on a pro forma basis as of December 31, 2018, and assuming full conversion of the Series A Preferred into common stock, the number of shares of common stock purchased by existing holders of our common stock, the number of shares to be purchased by new investors in this offering, the total consideration paid by existing holders or to be paid by new investors in this offering and the average price per share paid by existing holders or to be paid by new investors in the offering (before deducting estimated offering expenses that we must pay).

| | Shares Received | | Total Consi | Total Consideration | |
|---------------------------|-----------------|---------|---------------|---------------------|-----------------|
| Minimum Offering | Number | Percent | Amount | Percent | Price per Share |
| Existing Stockholders | 7,643,500 | 67.1% | \$764 | 0.005% | \$0.0001 |
| Investors in the Offering | 3,750,000 | 32.9% | \$15,000,000 | 99.995% | \$4.0000 |
| Total | 11,393,500 | 100.0% | \$15,000,764 | 100.000% | \$1.3166 |
| | Shares Re | eceived | Total Consi | deration | Average |
| | Shares Re | eceived | Total Const | deration | Average |
| Maximum Offering | <u>Number</u> | Percent | <u>Amount</u> | Percent | Price per Share |
| Existing Stockholders | 7,643,500 | 45.9% | \$764 | 0.002% | \$0.0001 |
| Investors in the Offering | 9,000,000 | 54.1% | \$36,000,000 | 99.998% | \$4.0000 |
| Total | 16,643,500 | 100.0% | \$36,000,764 | 100.000% | \$2.1631 |

The foregoing discussion and tables are based on the number of shares of common stock outstanding as of December 31, 2018, (assuming full conversion of the preferred stock sold in the offering) and exclude shares of common stock issuable upon exercise of stock options expected to be issued under the TransCode Therapeutics, Inc. 2019 Stock Option and Grant Plan, none of which had been awarded at the date of this PPM. We anticipate that the 2019 Option and Grant Plan will provide for awards equal to approximately 20% of our fully-diluted shares outstanding.

Dilution from Other Actions

Dilution can also result from future actions by a company. Besides possible dilution in net tangible book value, an investor's stake in a company could be diluted if the company issues additional shares in which case the percentage of the company owned will decrease unless investors purchase a *pro rata* percentage of the new shares sold. This sort of dilution may result even though the value of the company and the investor's shareholding may increase. Issuances of additional shares could result from a stock offering (such as, for example, through a private placement, an initial public offering, a crowdfunding round, a venture capital round, or an angel investment), employees exercising stock options, by conversion of certain instruments that are convertible into our stock, or by exercise of certain instruments that are exercisable for our stock. Examples of these types of instruments include convertible bonds, convertible preferred shares or warrants.

In addition, if a company issues more shares, there may also be dilution in earnings per share if earnings do not immediately increase sufficiently to offset the increase number of shares.

A type of dilution that can adversely affect early-stage investors such as in this offering can occur in the future if the company raises capital by selling new shares in a "down round." A down round is one in which the value of the company per share is lower than in earlier offerings. An example of how this might occur is as follows (the numbers used are for illustrative purposes only):

- In 2018, Jane invests \$20,000 for shares that represent 2% of a company valued at \$1 million.
- In 2019, the company sells \$5 million in shares to venture capitalists at a valuation (before the new investment) of \$5 million. Jane now owns only 1% of the company, but her stake is worth \$100,000.
- By 2021, the company has run into serious problems and, to stay afloat, raises \$1 million at a valuation (before the new investment) of only \$1 million (the "down round"). Jane now owns only 0.50% of the company and her stake is worth only \$10,000.

This type of dilution might also happen upon conversion of convertible notes into shares. Typically, the terms of convertible notes issued by early-stage companies provide that in the event of another round of financing, the holders of the convertible notes get to convert their notes into equity at a "discount" to the price paid by the new investors, i.e., they get more shares than the new investors would for the same amount invested. Additionally, convertible notes may have a "price cap" on the conversion price, which can effectively increase the discount. Either way, the holders of the convertible notes get more shares for their money than new investors. In the event that the financing is a "down round" the holders of the convertible notes will dilute existing equity holders even more than the new investors do because holders of the convertible notes get more shares for their money than do the new investors.

If you are making an investment expecting to own a certain percentage of the company or expecting each share to hold a certain amount of value, it's important to realize how the value of those shares can decrease for many reasons, including actions taken by the company. Dilution can materially and adversely affect the value of a share, ownership percentage, voting control, and earnings per share. Further, many other factors including those described in this PPM can materially and adversely affect the value of your investment in our securities.

BUSINESS

OVERVIEW

TransCode Therapeutics is a Boston based pre-clinical biopharmaceutical company focused on discovery, development and commercialization of a pipeline of innovative microRNA (miRNA) targeted therapeutics for treating cancer with an initial focus on metastasis. Virtually all cancers, including cancers of the blood and the lymphatic system (leukemia, multiple myeloma, and lymphoma), can form metastatic tumors, the most common being tumors in the lymph nodes, bone, liver, and lungs. Considering that approximately 9 out of 10 cancer deaths are due to metastasis and not primary tumors, we believe that there is a significant potential market for our therapeutics, if approved.

MARKET OVERVIEW

This year, it is estimated that more than 14 million people worldwide will learn they have cancer and nearly 9 million people will lose their lives to cancer. Cancer continues to be one of the leading causes of morbidity and mortality worldwide, but therapeutic innovation based on improved understanding of disease biology and translational research have considerably changed the treatment paradigm for many cancers.¹ However, despite the many therapies and the billions of dollars spent each year, existing cancer treatments are only incrementally improving patient outcomes for late stage disease. It is now widely known that nine out of ten cancer deaths are due to metastases and not the primary tumors from which they originate.

Traditional cancer therapy has often relied on a cytotoxic approach that views non-metastatic and metastatic tumor cells as identical in terms of molecular biology and sensitivity to therapeutic intervention. Mounting evidence suggests that, in fact, non-metastatic and metastatic tumor cells differ in key characteristics that could explain the capacity of the metastatic cells to not only escape the primary organ but also to survive while in the circulation and to colonize a distant organ. This therapeutic approach contributes to the notably poor outcomes in patients diagnosed with metastatic disease and represents a clear, unmet clinical need.

Conventional therapies aimed at treating primary tumor cell disease oftentimes do not affect the metastatic cell, resulting in poor outcomes in cancer patients diagnosed with metastatic disease. The scientific reason for this is that metastatic tumor cells are anatomically, biologically, and physiologically distinct from the primary tumor cells, especially in breast cancer, and therefore need to be treated differentially. The highly promising therapeutic strategy proposed by TransCode is centered around the targeting and eradication of metastatic tumor cells with the goal of dramatically improving outcomes in patients suffering from metastatic disease.

Metastatic cells are uniquely capable of leaving the primary tumor, surviving in circulation and colonizing a distant organ, with properties distinct from the primary tumor in which the cells originated. The hypothesis that TransCode's founders proposed is that cells endowed with that capability evolve in response to an adaptive process driven by a cellular "survival instinct". We

¹ Global Oncology Trends 2017. IQVIA Report, May 31, 2017

have identified and are therapeutically targeting a biological mechanism in metastatic cancers that we have termed "metastamiR dependence." Our research shows that metastatic tumor cells cannot survive without the overexpression of a specific non-coding RNA molecule, microRNA-10b, which regulates the viability of metastatic tumor cells. Without the high level of expression of microRNA-10b, these cells are stripped of their natural microenvironment and do not have the adaptive mechanism needed to survive.

The choice of microRNA-10b as a target is further supported by its potentially broad relevance to cancer. To date, more than 120 studies have been completed on the link between microRNA-10b and metastasis encompassing at least 18 cancer types, including breast, pancreatic, lung, colorectal, gastric, bladder, ovarian, hepatocellular cancer, glioblastoma and others. These studies provide evidence of the critical role played by microRNA-10b in metastasis and suggest that our approach can be broadly applicable to metastatic disease.

Against this conceptual framework, we have designed the first known cancer therapeuticcandidate, TTX-MC138, that efficiently inhibits microRNA-10b in metastatic cells, resulting in the regression of established metastatic lesions in distant vital organs, such as the liver, bone, lungs and brain.

Cancer represents a major area of concern for the healthcare industry. It is one of the leading causes of deaths all around the world. According to World Health Organization (WHO), cancer claimed 8.8 million lives in 2015 and accounted for almost 1 in 6 global deaths. In low- and middle- income countries about 70% of deaths are caused due to cancer, representing a significant burden on the global economy. The total annual economic cost of cancer treatment was estimated approximately \$1.16 trillion in 2010.²

Metastatic cancer, also termed stage IV (four) cancer, is the advanced form of cancer which has spread from an original tumor location to new sites in the body. Treatment of metastatic cancer is more complicated than treating early-stage cancer. Metastatic cancer is curable under certain situations, although most of the treatments are focused on providing palliative care. With increases in the prevalence of disease and in life expectancy, there is also a rise in research and development, or R&D, expenditures in the field of oncology. Additionally, several biopharmaceutical companies are trying to enter the market and are investing in oncology to meet the increasing needs of the metastatic cancer patients.

The global metastatic cancer treatment market was valued \$54.11 billion in 2017, and is anticipated to reach \$98.24 billion by 2025.³ Rising prevalence of cancer and high unmet medical needs of patients suffering from metastatic cancer are the drivers stimulating the growth of the metastatic cancer treatment market.

² Stewart BW, Wild CP, editors. World cancer report 2014; Lyon: International Agency for Research on Cancer; 2014.

³ Global Metastatic Cancer Treatment Market – Focus on Drugs, Competitive Landscape, and Country - Analysis and Forecast (2018-2025) BIS Research June 2018

PRODUCT-CANDIDATES LEAD THERAPEUTIC-CANDIDATE TTX-MC138

IONP + Inhibitory Oligonucleotide sequenced to miRNA-10b

- Eliminates metastasis by inhibiting microRNA-10b
- Inhibition results in death of metastatic tumor cells
- Proven delivery system optimized for designated target
- Image guided delivery key competitive advantage
- Unique capability to accumulate at metastatic sites

TransCode has designed the first known cancer therapeutic-candidate designed specifically for this novel therapeutic niche. In particular, our scientific co-founders have identified a new biological phenomenon that we term "metastamiR dependence". MetastamiR dependence is defined as the inability of metastatic tumor cells to survive without the overexpression of specific non-coding RNA molecules, called microRNAs. This phenomenon is exemplified by TransCode's lead therapeutic-candidate target, microRNA-10b, which has been found to specifically regulate the viability of metastatic tumor cells.

The mechanism behind metastamiR dependence relies on two key events. First, a small population of cells in the primary tumor overexpress microRNA-10b and, as a result, these same cells acquire the ability to migrate and invade surrounding tissues. After these cells have upregulated the expression of microRNA-10b, they become molecularly "dependent" on this high level of expression. Thus, we believe that once microRNA-10b expression is inactivated at the metastatic site, the metastatic tumor cells die.

TransCode's scientific co-founders have demonstrated that TTX-MC138 specifically inhibits microRNA-10b expression. The therapeutic-candidate has been pre-clinically validated in animal models of metastatic breast cancer. We showed that inhibition of microRNA-10b by TTX-MC138 led to the death of metastatic tumor cells and elimination of established metastases after just four to six weekly treatments. There was no evidence of recurrence for the lifetime of the animals and no systemic toxicity was observed.

The choice of microRNA-10b as a target is further supported by its potentially broad relevance to cancer. Recent studies have demonstrated that the influence of microRNA-10b extends beyond breast cancer and includes pancreatic, lung, colorectal, gastric, bladder, ovarian, and hepatocellular cancer amongst others, suggesting that the described approach can be broadly applicable to metastatic disease.

THERAPEUTIC CONCEPT

Our therapeutic concept is summarized in the diagram below.TTX-MC138 represents a proprietary therapeutic-candidate that inhibits microRNA-10b. In primary tumors, inhibition of microRNA-10b by TTX-MC138 leads to arrest of tumor cell dissemination to local and distant organs. A combination of TTX-MC138 with low dose doxorubicin leads to metastatic cell death



and complete and persistent regression of already formed metastatic lesions in local and distant organs.



INHIBITING microRNA-10b WITH TTX-MC138

TTX-MC138 arrests transit of metastatic tumors to local and distant organs; combining TTX-MC138 with a low dose of doxorubicin leads to regression of existing metastases.

POTENTIAL ADVANTAGES OF TTX-MC138:

- Image-based confirmation of tumor uptake (innately MRI-visible)
- Increased circulation half-life (24-36 hours in humans) vs. other delivery systems
- The Iron Oxide Nano Particle (IONP) delivery system has been clinically validated (in clinical practice for imaging for 25 years)
- No evidence of toxicity
- TTX-MC138 is hormone receptor independent and its mechanism of action has been shown to treat metastatic breast cancer in animals regardless of hormone receptor type (ER+/-, PR+/-, HER2+/-, or combinations thereof)

Our goal is to launch proprietary therapeutics that would cause lifelong regression of pre-existing metastases by treating patients with TTXMC138. In our pre-clinical studies, when TTX-MC138 was combined with a low-dose cytostatic (doxorubicin), there was complete and persistent regression of pre-existing metastatic cancer with no evidence of recurrence and no systemic toxicity. Doxorubicin was used to slow down cell division in tumor cells since the tumor model we used was extremely aggressive. In pre-clinical studies that utilized aggressive metastatic tumor models, the use of doxorubicin was necessary to allow TTX-MC138 to fully inhibit microRNA-10b. Because metastatic cell growth is slower in humans, the use of a cytostatic such as doxorubicin should not be necessary, and TTX-MC138 would be administered as a monotherapy. Combining TTX-MC138 with a cytotoxic in patients enrolled in our clinical trial is an option that we will discuss with the FDA at our pre-IND meeting.

Specifically, in mice with lymph node metastases from breast cancer, just four weekly treatments eliminated metastatic burden in all animals. As metastases were eliminated, the therapy was stopped (see below). No recurrence of metastatic disease was observed by the end of the study. This translated into 100% survival without evidence of toxicity.

STAGE II/III METASTATIC TRIPLE-NEGATIVE BREAST CANCER, MOUSE MODEL

- TTX-MC138 superior to control + low-dose doxorubicin*
- Eliminated pre-existing *local* metastases



STAGE IV METASTATIC TRIPLE-NEGATIVE BREAST CANCER, MOUSE MODEL

- TTX-MC138 superior to control + low-dose doxorubicin*
- Eliminated pre-existing *distant* metastases



Legend:

NT - No therapy C - Control (an irrelevant oligo) T - TTX-MC138 dox - low-dose doxorubicin

*Doxorubicin was used to slow cell division in tumor cells. In pre-clinical studies that utilized aggressive metastatic tumor models, the use of doxorubicin allowed TTX-MC138 to fully inhibit microRNA-10b. Because metastatic growth is slower in humans, the use of a cytostatic such as doxorubicin should not be necessary, and TTX-MC138 would be administered as a monotherapy.

PIPELINE

We plan to continue research on a variety of approaches targeting microRNA-10b and microRNAs in other cancer types including ovarian, pancreatic, prostate, non-small lung cancer, colorectal as well as glioblastoma. These cancers involve poor 5-year survival rates in patients with stage IV disease. We anticipate that TTX-MC138 will enter clinical trials in 2020 simultaneously with filing of our Investigational New Drug application, or IND, under fast track status with the FDA. If we receive regulatory approval to market TTX-MC138, we anticipate product launch in 2022. Patent expiry is expected to be in 2031 and we expect peak sales from years 2025 – 2031. We may be able to extend patent protection of our technologies through enhancements to existing patents. In addition, we are in the initial stages of licensing discussions with MGH regarding a promising therapeutic target, Lin28b for treatment of pancreatic cancer. We also intend to explore a silencing microRNA therapeutic created at MGH against PD-L1. The PD-L1 candidate has been tested by our co-founders in a preclinical model with encouraging results. There is no assurance that even if we successfully license any additional technologies, they will prove successful in further testing.

| Therapeutic | Target | Discovery | In vitro** | Preclinical | Phase II/III |
|------------------|---------|------------------------|------------|-------------|--------------|
| | miR-10b | MTNBC | | | |
| | miR-10b | Colorectal cancer | | | |
| TTX-MC138 | miR-10b | NSCL cancer | | | |
| | miR-10b | Pancreatic cancer*** | | | |
| | miR-10b | Glioblastoma** | | | |
| | miR-10b | Hepatocellular cancer* | ** | | |
| Lin28b Inhibitor | Lin28b | Pancreatic cancer*** | | | |
| anti-miR-xxx | miR-xxx | Other cancer types | | | |
| siRNA | PD-L1 | Pancreatic Cancer*** | | | |

Pipeline*

- * Pipeline currently in development selected therapeutics and targets may change
- TTX-MC138 demonstrated therapeutic efficacy in vitro in 77% of 624 human tumor cell lines representing the spectrum of metastatic and non-metastatic cancers.
 PLOS ONE | <u>https://doi.org/10.1371/journal.pone.0201046 July 2018</u>
- *** Cancer types classified as orphan diseases

PROPOSED CLINICAL PROOF OF CONCEPT

Achieving Proof of Concept (POC) in humans withTTX-MC138 would represent a key milestone. Our anticipated primary end points for clinical studies include elimination or

regression of metastatic burden and arrest of further metastatic spread. Depending on available capital, our options to determine efficacy and safety in patients are to either enroll and treat patients representing a single tumor type or to enroll and treat patients representing multiple tumor types using a "adaptive design" clinical trial as described below.

SINGLE TUMOR TYPE CLINICAL TRIAL

In this type trial, we would measure therapeutic efficacy of TTX-MC138 by treating up to 20 patients with Stage III-IV metastatic breast cancer (or other types of metastatic cancer determined at the time of the start of the clinical trial).

ADAPTIVE DESIGN CLINICAL TRIAL

In an adaptive design trial, we would determine therapeutic efficacy of TTX-MC138 by treating patients representing various different metastatic cancer types (number of patients and cancer types to be determined at the time of the trial and based on available capital resources to conduct such a trial).

Enroll and treat metastatic cancer patients (up to 6 different indications) with established metastases

- Expected treatment: 4-8 monthly injections (dosing TBD)
- Additional patients would be enrolled in one or more arms of the study demonstrating the greatest effectiveness in a particular cancer indication (as measured by MRI)

Clinical diagnosis:

- Stage IV metastatic cancer
- microRNA-10b over-expressed (measured by PCR and with TransCode's own biomarker test)
 - o Validate results with MRI of TTX-MC138 delivery

Clinical trial criteria will need to be established prior to choosing oncology investigators and investigator sites. In addition, the amount of capital we have available for clinical assessments of our therapeutic-candidates will also affect the criteria we use to assess treatment success. Trial criteria we may want to include in our patient studies:

PROPOSED PHASE IIA TRIAL CRITERIA (TO BE DETERMINED)

Key Inclusion Criteria:

- Patients with metastatic disease, recurrent or progressed while receiving chemotherapy
- High levels of circulating microRNA-10b

Key Exclusion Criteria:

- Presence of visceral crisis
- o Evidence or history of CNS metastasis
- Pregnancy

• Evidence of renal disease

Key Study Design Aspects:

- Adaptive trial design
- Primary endpoint Reduction in metastatic burden (radiologically detected)
- Key Secondary Endpoints:
- Progression Free Survival in 90 days
- o Disease Free Survival



PREDICTIVE BIOMARKER

A key factor in reducing mortality due to cancer has been early detection. One of the most promising features of microRNA-10b is the ability to use its expression as a diagnostic biomarker for the presence of metastases and a predictive biomarker of overall/disease free survival in cancer.

- Further development of models for analysis of biopsy samples will potentially allow the identification of patients at increased risk of progression, a capability not currently available.
- Using microRNA-10b as a prognostic factor in the analysis of the existing tumors and being able to stratify tumors based on aggressiveness should better inform the need for more aggressive treatment and/or the need for increased surveillance of patients.
- In addition to serving as a predictive biomarker for disease progression, microRNA-10b expression might also be useful as a diagnostic biomarker.
- Measuring the microRNA-10b levels of tumors before beginning treatment could better inform therapeutic decisions as evidenced in recent studies.
 - MicroRNA-10b expression is negatively correlated to sensitivity to 5-fluorouracil (5-FU)-based therapies; and
 - MicroRNA-10b expression can induce greater tamoxifen resistance.
- Another valuable use of this diagnostic method could be the ability to discriminate between high-risk and low-risk disease and the capability to identify the presence of metastasis.

TransCode Therapeutics has created a specific biomarker (companion) test that can quantify microRNA expression in patient serum or freshly biopsied tissue. Our companion test is intended to be used to measure the response to therapy with TTX-MC138 (for microRNA-10b). This capability could be important in determining which patients are likely to respond to therapy with TTX-MC138 and in measuring therapeutic response during and after treatment.

TransCode's microRNA nanosensor could address a major unmet need in the areas of cancer biology, diagnosis, and therapy by introducing a tool that could permit the analysis of microRNA expression in intact live cells and tissues. Current methods destroy the cell and therefore do not permit longitudinal studies that assess responses to therapy.

- The fluorescent read-out generated by the nanosensor is highly specific and has nanomolar sensitivity.
- The nanosensor assay is inexpensive and rapid. It can be used to determine microRNA expression in biopsies, serum, and circulating tumor cells, and for monitoring treatment response with TTX-MC138 in clinical trials.

POTENTIAL UTILITY OF BIOMARKER TEST



COMPETITION

The pharmaceutical industry intensely competitive and constantly evolving. While we believe that our expertise in microRNA-10b therapeutic-candidates, scientific knowledge and intellectual property provide us with certain competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies (see table below). Most of our potential competitors are larger companies than we are, and they have substantially greater capital and human resources than we do, along with established market positions and expertise and capabilities in sales, marketing, distribution, clinical trials and regulatory matters. Not only must we compete with other companies that are focused on miRNA therapeutics, but also any product-candidates that we successfully develop and commercialize must compete with existing therapies and new therapies that may become available in the future. There are several companies operating in the "targeted therapy" space, many of which have been around for longer with the advantages described above. A selected list of our most significant competitors and their products is presented below:

| Treatment Ontion | Therapy Type | Specific Drug | Company | Drug action |
|---------------------|---|------------------------|--------------------------------|--|
| Systemic Therapy | Endocrine Therapy | | | |
| | Selective estrogen receptor modulators (SERM) | | | ER and or PR+ |
| | | Tamoxifen | AstraZeneca Pharmaceuticals | |
| | | Raloxifene | Ely Lilly | |
| | | Bazedoxifene | Pfizer Pharmaceuticals | |
| | | Toremifene | GTx Inc. | |
| | Aromatase inhibitors | | | Reduce estrogen levels |
| | | Anastrozole (Arimidex) | AstraZeneca Pharmaceuticals | |
| | | Letrozole (Femara) | Novartis Oncology | |
| | | Exemestane (Aromasin) | Pfizer Pharmaceuticals | |
| | | Vorozole (Rivizor) | | |
| | | Formestane (Lentaron) | | |
| | | Fadrozole (Afema) | Novartis Oncology | |
| | Pure anti-estrogens | | | Block influence of estrogen on BC cells |
| | | Fulvestrant | AstraZeneca Pharmaceuticals | |
| | | Megestrol Acetate | PAR Pharmaceuticals | |

| | Chemotherapy | | | Slow/stop tumor cell growth |
|------------------|---|--|------------------------|--|
| | | Cyclophosphamide (C) | | 8 |
| | | Docetaxel (T) | Sanofi Aventis | |
| | | Doxorubicin (A) | lanssen | |
| | | Epirubicin (F) | Pharmacia | |
| | | Methotrevate (M) | Generic | |
| | | Paclitavel (T) | Generic | |
| | | Capocitabino | Generic | |
| | | Capecitabilie | Bristol Myors Squibb | |
| | | Carbonlatin | (Conoric now) | |
| | | Plating | Rristol Myors Squibb | |
| | | Ciculatin | Bristol Myers Squibb | |
| | | Cispiatin | Bristor Wyers Squibb | |
| | | E atte a the | (Generic now) | |
| | | | Elsal Co. | |
| | | 5-FIUOROURACII (5FU OR | Generic | |
| | | Gemcitabine | Fli Lilly | |
| | | Ixabenilone | Bristol Myers Souibh | |
| | | Vinorelhine | Glaxo SmithKline | |
| Targeted Therany | Tyrosine kinase | VIIIOICIDIIIC | | HFR2+ |
| Targeteu merapy | Inhibitors | | | TIENZ' |
| | | Lapatinib (Tykerb) | Glaxo SmithKline | |
| | PARP Inhibitors | Iningrih (offer dining) | Canafi | Block the PARP enzyme, involved in DNA repair. Lower chances for cancer cells to become resistant to chemotherap y |
| | | trial failures company stopped its production) | Sanoti | |
| | | Rucaparib | Clovis Oncology | |
| | Cyclin dependent kinase 4,6 Inhibitors | | | ER+,PR+ HER2- |
| | | Palbociclib | Pfizer Pharmaceuticals | |
| | P13 Kinase inhibitors | | | ER+ |
| | | Pictilisib (in clinicals – no sufficient improvement seen) | Roche | |
| | Anti-angiogenesis drugs | | | Blocks growth of new blood vessels |
| | | Bevacizumab | Genentech | |

THERAPEUTIC DELIVERY SYSTEM

To inhibit miRNA-10b in metastatic cells, it is necessary to deliver oligonucleotides that would bind to this microRNA and inhibit or inactivate it. To effect delivery, we use image-capable magnetic nanoparticles and conjugated antisense locked nucleic acid oligos (or LNAs). We have extensively studied the delivery nanoparticle's step-by-step synthesis and characterization, as well as their hydrodynamic size, surface charge, relaxivity, toxicity, stability and immunogenicity.

We describe our delivery system as "Inhibitory Oligonucleotide Conjugated Nanoparticle" and believe it offers the following advantages:

- Small nanoparticle (20nm)– gains access to interstitial area within tumor cells;
- Highly stable in solution;
- Low toxicity potential;
- Low immunogenicity; and
- Employs locked nucleic acid oligos for greater binding affinity and specificity.

INTELLECTUAL PROPERTY

Patents for the therapeutic and the biomarker test have issued, and we recently signed an exclusive world-wide license with Massachusetts General Hospital Corporation, or MGH, for this intellectual property, or IP. The MGH patents for the therapeutic were filed only in the US, which we believe represents 80% or more of the total market. The patent for the biomarker test has issued in the US, and we are currently pursuing its patent rights in territories outside the US. We intend to file additional patent applications to broaden our IP portfolio coverage.

PATENTS

Therapeutic Patents

Therapeutic Nanoparticles and Methods of Use Thereof

- 2014/0241996 Composition of Matter for TTX-MC138
 - (Expected to issue in early 2019). Expires 2031.
- US 9,629,812 Method Patent (Issued April 2017). Expires 2031.

Biomarker Patents

miRNA Profiling Compositions and Methods of Use

- US 10,086,093 Nanosensor for non-invasive detection of microRNA activity (Issued October 2018). Expires 2033

RESEARCH AND DEVELOPMENT

While at MGH, our scientific co-founders received approximately \$5.3 million for research on TTX-MC138, primarily from government grants. Research conducted with the grant funds includes:

• Optimized design of the therapeutic-candidate targeting microRNA-10b.

- Employed the therapeutic-candidate to demonstrate complete prevention of metastasis.
- Demonstrated that TTX-MC138 completely arrests the expansion of already formed metastases.
- Discovered and validated novel context-dependent biology of microRNA-10b specific to metastatic cells.
- Developed therapeutic-candidate protocol combining TTX-MC138 and low dose chemotherapy.
- Demonstrated complete regression of established lymph node metastases.
- Investigated and validated the basic biology behind metastatic regression by TTX-MC138.
- Discovered the novel role of microRNA-10b as essential master regulator of the viability of metastatic tumor cells.
- Discovered the phenomenon of "metastamiR addiction".
- Demonstrated successful delivery of the therapeutic-candidate to distant metastases.
- Demonstrated regression of lung metastases by combining TTX-MC138 and low dose doxirubicin.

The foregoing research results were obtained in laboratory studies and may not be obtained if and when we test TTX-MC138 in humans.

IND ENABLING PROCESS

An Investigational New Drug Application (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. In addition, current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because we want to ship our investigational drug to clinical investigators in many states, we must seek an exemption from that legal requirement. The IND Application is the means through which we obtain this exemption from the FDA. Once Series A funding is achieved, we will begin the IND enabling process for its lead therapeutic TTX-MC138 through our development partners in order to obtain an IND for its First in Man trials.

On a parallel path, we also intend to continue pre-clinical research on new therapeutics and biomarkers in order to expand our oncology portfolio. Our founders have vast experience in obtaining funds from NIH and other agencies. However, the process of obtaining funds through grant submissions can take up to a year or more and may not be successful, hence the necessity to raise outside capital. Use of grant monies would only be earmarked for pre-clinical studies in animals that would otherwise not be completed using capital raised under our Series A Preferred offering.

Pharmacology

In vitro target modulation studies will be used to demonstrate *in vitro* activity using cell-based systems. These data will be used to show that the therapeutic-candidate has measurable activity to support proof of concept.

Demonstration of *in vivo* activity will be done using murine cancer models investigating the dose-related response for TTX-MC138, as well as to obtain supporting information on the relative tolerability of active doses in murine models. Analytical methods to assess exposure will be investigated to determine the feasibility of assessing typical pharmacokinetic, or PK, parameters in the animal model studies as well as in the toxicology studies.

ADME

All of the typical small molecule ADME (Absorption/Distribution/Metabolism/Excretion) studies will not need to be conducted.

Analytical methods will be developed to quantify dose formulations of TTX-MC138, as well as attempting to measure circulating concentrations post-treatment in the animal efficacy and toxicology studies. Where possible, these methods will be validated using the current "Crystal City Guideline" standards.

Special studies: recently, companies filing US IND's for microRNA therapeutics have been required to add studies investigating the potential for inhibition of cytochrome P450 (CYP450) enzyme systems. Studies to investigate interaction with transporters will also be required. Further, it might be necessary to assess the characteristics of cell permeation of conjugated oligonucleotides versus free oligonucleotides. These studies will be added as required.

BIOANALYTICAL

Two bioanalytical methods are needed as part of the IND enabling plan, one is a method for the quantification of TTX-MC138 in buffer systems used to assess *in vitro* activity, or dose formulations for *in vivo* dosing, and second is a method for quantifying TTX-MC138, or surrogate, in circulation (i.e., serum or plasma) of dosed animals to assess PK.

PHARMACOKINETICS

The pharmacokinetics of TTX-MC138 will need to be described in all animal species used to investigate efficacy or safety. The current plan employs murine models for efficacy, and rat and monkeys for use in the toxicology program. Since it is not likely that the oligonucleotides will have activity in non-human cells, the use of rodents in the toxicology program may not be necessary, therefore, we do not plan to develop an analytical method for use with rats.

TOXICOLOGY

Typically, rodent and non-rodent species must be used to characterize possible toxicity of new therapeutic-candidates in humans. It is likely that both species will not be required for TTX-MC138, since human oligonucleotides are not active in rodents. Only investigation into the tolerability and safety of TTX-MC138 in cynomolgus monkeys is expected to be needed. Two toxicology studies will be conducted, a non-GLP (Good Laboratory Practice) dose range finding (DRF) study (up to 14-days), followed by a GLP compliant 28-day toxicology study, with two-

week recovery and toxicokinetics (TK). There may be a rationale for extending this study for one week to obtain five weeks of twice-weekly dosing to extend coverage for clinical support.

REGULATORY

There are at least two direct interactions expected to occur with the US Food and Drug Administration, or FDA. One is a pre-IND (PIND) meeting and the second is the filing of the IND.

CHEMISTRY, MANUFACTURING AND CONTROLS (CMC)

This is the most extensive aspect of the IND enabling process. CMC is critical to setting appropriate timelines and connecting "deliverables" with human trial start dates. Deliverables are more than just the drug product itself. They also include analytical standards and required documentation on drug purity, dose strength, storage, handling and stability. The materials for the analytical development process are produced as part of the CMC process and must be delivered before that work can begin, as are activities that require analytical support which must also be timed accordingly.

DEVELOPMENT PLAN TIMELINE



TransCode expects to file an IND under breakthrough status with the FDA once funded. Planned additional pre-clinical and clinical target validations to be conducted with microRNA-10b for additional metastatic cancer targets are shown in the pipeline diagram below.

We will also begin work in the following areas prior to submission of the New Drug Application, or NDA:

• Clinical Protocols and Investigator Information - Detailed protocols for our proposed clinical studies to assess whether the initial trials will expose subjects to unnecessary risks. Also, we will obtain information on the qualifications of our selected clinical

investigators to ensure they are qualified to fulfil their clinical trial duties. Finally, commitments to (i) obtain informed consent from research subjects (ii) obtain review of the study by an institutional review board (IRB), and (iii) adhere to IND regulations.

- Follow-up work will be conducted in good manufacturing practices, or GMP, synthesis with our chosen manufacturing partner as well as others we identify.
- FDA approval for a Phase IIa adaptive design clinical trial of TTX-MC138 in multiple metastatic cancer indications.
- Determine primary end-points to be achieved in the clinical trial including disease regression with primary outcome measurements in expansion cohort providing proof-of-concept in up to 120 patients in an adaptive trial design assessing the effect of TTX-MC138 in patients with various late stage metastatic cancer indications.
- TransCode believes that imaging can be used as a Pharmacodynamic marker to establish the dose-tumor uptake relationship to support clinical trial dose selection.

We intend to involve one of the major clinical research organizations, or CRO's, to assist with optimizing our Phase IIa development plan and incorporating PK/PD strategies into our development plan.

MILESTONES

We estimate that the minimum offering of \$15 million would fund us into 2021 during which we anticipate completion of the following milestones:

- European Patent to issue for biomarker sensor
- Hire essential employees and contractors/consultants
- Contract with Oligonucleotide manufacturer
- Contract for final development of TTX-MC138
- In-license other assets
- File new patents
- Manufacture the necessary quantities of non-GMP TTX-MC138 for completion of the Pre-IND enabling studies and of current GMP, or cGMP, TTX-MC138 for final toxicity studies and for the first in human clinical study.
- Complete Pre-IND enabling studies, including the toxicity assessment in animals.
- Receive FDA approval of our first in human clinical study.

We estimate that the maximum offering of \$36 million would fund us through Proof of Concept and anticipate achievement of the following additional milestones:

- Hire a CRO to plan our FIM study, including determining possible trial sites, physician investigators, number of subjects and tumor types.
- Enroll subjects; dose subjects; measure outcomes and analyze data versus expected endpoints.
- Achieve clinical Proof-of-Concept of TTX-MC138 in a PhIIa adaptive design clinical trial involving 100 or more subjects in up to six cancer types.
- File an NDA for TTX-MC138 in at least one cancer type.

Assuming achievement of certain milestones with \$36 million from the Series A Preferred, we may expand therapeutic indications for TTX-MC138 and expand our research and development, or R&D, efforts to develop new products. Expanded R&D would likely require additional capital. Additional capital could be sought through any combination of strategic partnership(s) with other biopharmaceutical companies, private financings, a public offering, and government or other grants.

REGULATORY

We operate in a highly regulated business. The significant risks relating to this circumstance are discussed in "Risk Factors" and below. Our regulatory consultants have broad knowledge of and experience in clinical research, product development and clinical testing in the context of FDA regulatory requirements. Their principal mission is to help FDA-regulated organizations accurately assess FDA regulatory requirements, risks and how to best manage the regulatory process.

CLINICAL AND PRECLINICAL TRIALS

Before obtaining approvals from regulatory authorities, including the FDA, to market our therapeutic-candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product-candidates in humans and an acceptable risk/benefit profile.

We have yet to begin any clinical trial and there is no assurance that we will ever conduct any clinical trial. Further, the outcome of preclinical testing and early clinical trials may not predict the success of later-stage clinical trials, and interim trial results do not necessarily predict final results. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and even if our clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do. Additional clinical trials could be required before we submit our therapeutic-candidate for approval. Many companies that believed their product-candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of those product-candidates. To the extent that the results of our trials are not satisfactory to the FDA or foreign regulatory authorities, approval of our product-candidates may be significantly delayed, or we may be required to conduct additional clinical trials, which would involve significant additional resources which may not be available to us. Even if we complete all required clinical trials, we may never obtain regulatory approvals to market any product-candidate.

THE FDA APPROVAL PROCESS

We have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA, and, as a company, we have no experience in obtaining approval of any product-candidate. The time required to obtain FDA and other approvals is unpredictable but typically takes one or more years following completion of clinical trials, depending upon the type, complexity and novelty of the product-candidate. We may encounter delays or rejections during any stage of the regulatory review and approval

process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of a product-candidate to meet, FDA requirements for safety, efficacy and quality.

The standards that the FDA and its foreign counterparts use when regulating us are not always applied predictably or uniformly and can change. Because the drugs we are developing may represent a new class of drug, the FDA and its foreign counterparts have not yet established any definitive policies, practices or guidelines in relation to these drugs. The lack of policies, practices or guidelines may hinder or slow review by the FDA of regulatory filings that we may submit. Moreover, the FDA may respond to these submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in and added costs for the clinical development of our product-candidates.

Any analysis of data from preclinical and clinical activities that we perform is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

In addition, the FDA may delay, limit, or deny approval of a product-candidate for many reasons, including:

- disagreement with the design or implementation of clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product-candidate is safe and effective for any indication;
- we may be unable to demonstrate that a product-candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the results of our clinical trials may not demonstrate the safety or efficacy required by the FDA for approval;
- the FDA may find deficiencies in our manufacturing processes or facilities; and the FDA's approval policies or regulations may significantly change in a manner rendering our clinical data insufficient for approval.

After submission of an NDA, the FDA may refuse to review the application, deny approval of the application, require additional testing or data or, if the NDA is filed and later approved, require post-marketing testing and surveillance to monitor the safety or efficacy of a product. Under the Prescription Drug User Fee Act (PDUFA), the FDA has agreed to certain performance goals in the review of NDAs. The FDA's timelines are flexible and subject to change based on workload and other potential review issues which may delay FDA's review of an NDA. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we desire which could affect the marketability of our products.

Even if we comply with all FDA regulatory requirements, we may not obtain regulatory approval for any of our product-candidates. If we fail to obtain regulatory approval for any of our product-candidates, we will have fewer commercialized products than we anticipate and correspondingly lower revenue.

In addition, because there may be approved treatments for some of the diseases for which we may seek approval of one of our product-candidates, in order to receive regulatory approval, we may need to demonstrate through clinical trials that our product-candidate is not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs, and the FDA's standards, especially regarding drug safety, appear to have become more stringent.

Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product-candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy, or REMS, plan as part of or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

If we or any collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. Enforcement actions can include, among others:

- adverse regulatory inspection findings;
- warning letters;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on, or prohibitions against, importation or exportation of our products;

- suspension of review or refusal to approve pending applications or supplements to approved applications;
- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for our products;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

In addition, if any of our products cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease;
- our reputation may suffer generally both among clinicians and patients; or
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a REMS in connection with approval, if any.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that our products are unlikely to receive regulatory approval or unlikely to be successfully commercialized.

ONGOING REGULATORY REQUIREMENTS

If we obtain regulatory approval for TTX-MC138 or any other product-candidate, we will only be permitted to market the approved product for the indication approved by FDA. Such approval may involve limitations on the indicated uses or promotional claims we may make for our products or otherwise preclude labeling that sufficiently differentiates our product from competitive products with comparable therapeutic profiles. For example, we may not be able to claim that our product has fewer side effects or improves compliance or efficacy unless we can demonstrate those attributes to FDA in clinical trials.

Later discovery of previously unknown problems with our product, including adverse events, or AEs, of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product; and
- injunctions, the imposition of civil penalties or criminal prosecution.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our productcandidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 and we may not achieve or sustain profitability.

In addition, if we pursue, and ultimately obtain, accelerated approval of TTX-MC138 based on a surrogate endpoint, the FDA would require us to conduct a confirmatory trial to verify the predicted clinical benefit as well as additional safety studies. The results from the confirmatory trial may not support the clinical benefit, which would result in the approval being withdrawn.

THIRD-PARTY REGULATORY REQUIREMENTS

To help ensure safety of medical products used with humans in the U.S., FDA has adopted current good manufacturing practice regulations. Similar regulatory requirements exist outside the United States.

Contract manufacturers we may use to manufacture our products and product-candidates must comply with cGMPs and are subject to continual review and periodic inspections to assess this compliance. Accordingly, although we are not involved in the day-to-day operations of our contract manufacturers, we are ultimately responsible for ensuring that our products and productcandidates are manufactured in accordance with cGMPs. We and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, quality control and quality assurance. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product-candidates or approved products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Any performance failure on the part of our contract manufacturers, or any interruption, poor yield or poor quality of manufactured materials, could delay clinical development, marketing approval, or sales of approved products. We do not currently have arrangements in place for second sources of supply. If any one of our contract manufacturers does not perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our products and product-candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our research and development activities involve use of potentially hazardous substances, including chemical and biological materials, by our contract manufacturers. If our contract manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our contract manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with regulatory standards, we cannot eliminate the risk of contamination or injury resulting from use or misuse of medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, state or federal authorities may curtail our use of these materials or otherwise interrupt our operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

ADDITIONAL REGULATORY REQUIREMENTS

We are or may in the future be subject to federal, state, and foreign healthcare laws and regulations pertaining to, among other things, fraud and abuse and patients' rights. These laws and regulations include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the U.S. federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- the U.S. federal Health Insurance Portability and Accountability Act (HIPAA), which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud healthcare programs;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which imposes requirements relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to

the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis; and

• state laws comparable to each of the above federal laws, such as, for example, antikickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient data privacy and security. Other state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

SUPPLIERS

Once funded, we will seek to contract with the manufacturing partners we have identified for the two components of TTX-MC138 – the iron-oxide nanoparticle (IONP) formulation that is conjugated to the Oligonucleotide that is specific to microRNA-10b. We have built relationships over the last two years with multiple component manufacturers to ensure we have primary and secondary suppliers of these essential components.

EMPLOYEES

As of the date of this PPM, we had two full-time employees, our President and Chief Executive Officer and our Vice President of R&D. To date, neither has received salary compensation or any customary benefits of employment. We had three part-time employees or consultants who filled employee roles. Our board of directors comprised three members and we had nine corporate and scientific advisors. Our founders, employees, directors and advisors are primarily based in Massachusetts.

LITIGATION

We are not involved in any litigation, and we are not aware of any threatened legal actions against us.

PROPERTY

We do not own any real estate or significant assets. We do not have a physical office but intend to lease one in the greater Boston, Massachusetts, area upon completion of this offering.

SUMMARY FINANCIAL INFORMATION

TransCode Therapeutics is a "C" corporation that was incorporated in the state of Delaware on January 11, 2016. Our financial statements at or for the years ended December 31, 2016 and 2017, have been audited by IndigoSpire CPA Group, LLC. Financial data for those periods or dates is presented below. Financial data at or for the nine months ended September 30, 2017 and 2018, shown below is from our unaudited financial statements.

STATEMENTS OF FINANCIAL CONDITION DATA

| | September 30, | | | | December 31, | | | |
|-------------------------------|---------------|-------------------|------|----------|--------------|----------|------|----------|
| | 2018 | | 2017 | | 2017 | | 2016 | |
| ASSETS | | unau | | | | | | |
| Current Assets | | | | | | | | |
| Cash & Cash Equivalents | | | | | | | | |
| Checking - Operating | \$ | 16,378 | \$ | 171 | \$ | 120 | \$ | 430 |
| Savings - Operating | \$ | 376,798 | \$ | - | \$ | - | \$ | - |
| Total Cash & Cash Equivalents | \$ | 393,176 | \$ | 171 | \$ | 120 | \$ | 430 |
| Deposits | \$ | 5,000 | \$ | - | \$ | 5,000 | \$ | - |
| TOTAL ASSETS | \$ | 398,176 | \$ | 171 | \$ | 5,120 | \$ | 430 |
| LIABILITIES AND EQUITY | | | | | | | | |
| Current Liabilities | | | | | | | | |
| Payables & Accrued Expenses | \$ | - | \$ | 9,000 | \$ | 23,336 | \$ | 9,000 |
| Due to Related Parties | \$ | 35,685 | \$ | 32,108 | \$ | 38,526 | \$ | 25,111 |
| Total Current Liabilities | \$ | 35,685 | \$ | 41,108 | \$ | 61,862 | \$ | 34,111 |
| Long-Term Liabilities | | | | | | | | |
| Notes Payable - Convertible | \$ | 550,000 | \$ | - | \$ | - | \$ | - |
| Total Long-Term Liabilities | \$ | 550,000 | \$ | - | \$ | - | \$ | - |
| Total Liabilities | \$ | 585,685 | \$ | 41,108 | \$ | 61,862 | \$ | 34,111 |
| Equity | | | | | | | | |
| Common Stock | \$ | 785 | \$ | 698 | | 764 | \$ | 564 |
| Retained Earnings | \$ | (57 <i>,</i> 337) | \$ | (34,245) | \$ | (34,245) | \$ | - |
| Net Income | \$ | (130,879) | \$ | (7,390) | \$ | (23,092) | \$ | (34,245) |
| Accumulated Deficit | \$ | (188,217) | \$ | (41,635) | \$ | (57,337) | \$ | (34,245) |
| Treasury Stock | \$ | (77) | \$ | - | \$ | (169) | \$ | - |
| Total Equity | \$ | (187,509) | \$ | (40,937) | \$ | (56,742) | \$ | (33,681) |
| TOTAL LIABILITIES AND EQUITY | \$ | 398,176 | \$ | 171 | \$ | 5,120 | \$ | 430 |

STATEMENTS OF OPERATIONS DATA

| | Nine Mont | hs Ended | | |
|----------------------------|--------------|-------------|-------------|--------------|
| | Septemb | er 30, | Year Ended | December 31, |
| | <u>2018</u> | <u>2017</u> | <u>2017</u> | <u>2016</u> |
| | unaudi | ted | | |
| REVENUES, net | \$- | \$- | \$- | \$- |
| OPERATING EXPENSES | | | | |
| General and Administrative | \$ 130,916 | \$ 7,390 | \$ 23,092 | \$ 34,245 |
| Total Operating Expenses | \$ 130,916 | \$ 7,390 | \$ 23,092 | \$ 34,245 |
| OPERATING LOSS | \$ (130,916) | \$ (7,390) | \$ (23,092) | \$ (34,245) |
| OTHER INCOME (EXPENSE) | \$ 37 | \$ - | \$ - | \$ - |
| NET LOSS | \$ (130,879) | \$ (7,390) | \$ (23,092) | \$ (34,245) |

STATEMENTS OF CASH FLOWS DATA

| | | Nine Mon | ths End | ded | | | | | |
|---|---------------|-----------|---------|---------|---|-------------------------|----|----------|--|
| | September 30, | | | | | Year Ended December 31, | | | |
| | 2018 | | 2017 | | | 2017 | | 2016 | |
| | unaudited | | | | | | | | |
| OPERATING ACTIVITIES | | | | | | | | | |
| Net Income | \$ | (130,879) | \$ | (7,390) | | 5 (23,092) | \$ | (34,245) | |
| Adjustments to reconcile Net Income to net cash | | | | | | | | | |
| provided by operations: | | | | | | | | | |
| Increase in Deposits | \$ | - | \$ | - | 9 | 5 (5,000) | \$ | - | |
| Increase in Accrued Expenses | \$ | (23,336) | \$ | - | 9 | 5 14,336 | \$ | 9,000 | |
| Total Adjustments | \$ | (23,336) | \$ | - | | 5 9 <i>,</i> 336 | \$ | 9,000 | |
| Net cash provided by operating activities | \$ | (154,215) | \$ | (7,390) | 5 | 5 (13,756) | \$ | (25,245) | |
| FINANCING ACTIVITIES | | | | | | | | | |
| Increase (Decrease) in Due to Related Parties | \$ | (2,841) | \$ | 6,996 | 9 | 8,415 | \$ | 25,111 | |
| Proceeds from Issuances of Notes Payable | \$ | 550,000 | \$ | - | | 5,000 | \$ | - | |
| Repayments of Notes Payable | \$ | (5,000) | \$ | - | | | \$ | - | |
| Proceeds from Sales of Common Stock | \$ | 21 | \$ | 135 | | 200 | \$ | 564 | |
| Repurchases of Common Stock | \$ | 92 | \$ | - | | (169) | \$ | - | |
| Net cash provided by financing activities | \$ | 542,272 | \$ | 7,131 | | 5 13,446 | \$ | 25,675 | |
| NET CHANGE IN CASH | \$ | 388,057 | \$ | (260) | : | 5 (310) | \$ | 430 | |
| Cash at beginning of period | \$ | 120 | \$ | 430 | | <u> </u> | \$ | _ | |
| CASH AT END OF PERIOD | \$ | 388,177 | \$ | 171 | _ | 5 120 | \$ | 430 | |

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

RESULTS OF OPERATIONS

TransCode has developed a potential therapy for metastatic cancer that in animal testing demonstrated complete regression and lifetime remission of metastatic tumors after four to six weekly treatments. This novel and highly promising therapeutic strategy against cancer relies on specific eradication of metastatic tumor cells – cells that have acquired the ability to escape into the circulation, survive during transit, and colonize a distant vital organ, such as the lungs or brain. In animal testing, these therapies spared healthy organs and showed essentially no systemic toxicity unlike traditional chemotherapy.

As a development stage company, we have no revenues and, thus, no costs of goods sold. Our primary expenses are for General and Administrative expenses necessary to operating the Company and for preparing to seek capital through the offering of our Series A Preferred. Expenditures for General and Administrative expenses in all periods described below resulted in net losses as shown at "Statements of Operations Data."

Nine months ended September 30, 2018, compared to nine months ended September 30, 2017

Total General and Administrative expenses in the 2018 period were approximately \$131,000, an increase of approximately \$124,000 or 17 times compared to the amount in the 2017 period. Substantially all the increase related to costs of professional services, primarily for legal fees and marketing services related to preparation for the Series A Preferred offering as well as for consulting and advisory services related to the design and development of our website.

Year ended December 31, 2017, compared to period from inception through December 31, 2016

Total General and Administrative expenses in 2017 were approximately \$23,000, a decrease of approximately \$11,000 or 33% compared to the amount in the 2016 period. Substantially all the decrease related to reduced legal expenses. As a result of the foregoing, our net loss for fiscal year 2017 was \$23,092 compared with \$34,245 in the 2016 period.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2018, the Company's cash on hand was approximately \$217,145.

Our current cash is not sufficient to fund our business plan as described in this PPM. We seek funding through the sale of our Series A Preferred to provide the resources necessary to advance our development program. Even if we raise the maximum amount in the offering, we expect to need additional capital to further advance our business.

To date, our activities have been funded by capital raised from sales of convertible promissory notes and from loans and advances from officers and shareholders. The balance of advances from founders and directors at December 31, 2017 and 2016, totaled \$38,526 and \$25,111, respectively. Portions of these advances were repaid in 2018 and the remainder is expected to repaid with funds from the offering.

DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES

Robert Michael Dudley, Co-Founder, Chief Executive Officer, Director

Michael has over 35 years of healthcare executive business experience in management, marketing, business development, finance, operations, as well as scientific and clinical expertise in multiple healthcare market sectors. Michael's expertise is in assessing business opportunities, defining business strategies, building supporting management, sales and marketing infrastructure, and managing execution. He also has extensive early stage, rapid growth, and large company executive management experience. Michael co-founded TransCode in January 2016 with Dr. Anna Moore and Dr. Zdravka Medarova. Prior to founding TransCode, beginning in 2012, Michael co-founded and was CEO and Chairman of Artemes Technologies, Inc. a Boston-based drug delivery technology company that specialized in customized drug delivery systems for injectable medications.

Michael began his career as a Cancer Research Associate at Harvard Medical School conducting immunology and biochemistry research in the field of tumor-associated blocking factors in breast cancer. Transitioning to the medical device field, he held executive level positions with industry leaders such as Abbott Diagnostics (Division of Abbott Labs), Imed Corporation, Spacelabs Medical, Smith & Nephew, Surgical Dynamics (division of TYCO) and Onux Medical (sold to CR Bard).

Michael's business expertise includes developing corporate mission and vision plans, acquisitions and integrations of acquired companies, strategic planning and analysis, and staff development. Michael is experienced in many areas of healthcare company operations, finance, manufacturing, sales and marketing management including recruitment and management of personnel, sales analysis, forecasting, product strategy and positioning, and P&L responsibility. Michael has guided dozens of medical products through the FDA and CE mark approval process as well as launching dozens of new products globally after approval.

Michael also has extensive experience in global clinical trial management (setting up investigative sites and investigators) for several products and as a Director of business development at one of the first web-based clinical trial companies, Phase Forward Inc. in Boston.

Thomas A. Fitzgerald, Chief Financial Officer, Director

Tom served Chief as Financial Officer of Velico Medical full-time from August 2006 until October 2017, and part-time until December 2018. Tom has extensive financial management experience with life sciences companies as an investment banker, chief financial officer and as a consultant to emerging growth companies. He was founding Managing Director for the healthcare investment banking firm of Leerink Partners (f/k/a Leerink Swann) where he raised capital in both the private and public markets and completed mergers, acquisitions and other strategic transactions. Tom serves as part-time Chief Financial Officer for two other early stage life sciences companies. He graduated with an M.B.A. from the Harvard University Graduate

School of Business Administration and an A.B. in Economics from Stanford University. Tom served in the U.S. Army for nearly four years, initially as an enlisted man on tanks and, subsequently, an airborne-qualified infantry officer.

Philippe P. Calais, PhD, Director

Dr. Calais has over 30 years of biotech and pharmaceutical industry experience both in North America and Europe, and for the past 6 years served as the president and chief executive officer of Isarna Therapeutics B.V. ("Isarna"), a developer of oligonucleotide therapeutics in Germany, Netherlands and USA. Prior to Isarna Therapeutics, Dr. Calais was the President and CEO of Univalor, one of the largest technology transfer organizations in North America, located in Montreal, Canada. Dr. Calais has been a Director of CohBar, Inc. since June 6, 2018 and has been an Economic Advisor to the French government since 2013. Dr. Calais served as Chief Executive Officer, President and Director of Ambrilia Biopharma, Inc., from January 1, 2008 to July 2009. He served as President Global Business of Neurochem Inc from January 2003 to December 31, 2007, focusing on corporate strategic positioning and company deployment. His management expertise, combined with extensive experience with pharma companies such as ICI Pharmaceuticals, Servier Canada and Roche (Switzerland and USA) covers the full scope of the drug chain - from discovery to clinical development, commercialization and sales optimization strategies as well as partnership and franchise strategic marketing for several therapeutic areas. He served as Chairman of the Board of Neurochem International, a wholly owned subsidiary of Neurochem. He was an Independent Director at Marina Biotech. Inc. from January 1, 2017 until May 2, 2018, and its Lead Independent Director since October 2, 2017. He served as Director of Canada's Research Based Pharmaceutical Companies, the Cité des Biotechs de Laval as well as several other biotech companies.

Dr. Calais received his bachelor's degree in pharmacy and his doctor of pharmacy from the Universite Francois-Rabelais in Tours, France, in 1985 and 1987, respectively.

Oliver C. Steinbach, PhD, Vice President R&D

Oliver is a research and development leader with extensive preclinical and clinical experience in product and solution creation especially through collaborations and alliances in the pharmaceutical, diagnostics and medical technology industries. His extensive career experience includes Drug (small-molecule/biologics/nucleic acid-based) and Biomarker Development; (Companion) Diagnostics (IVD, NGS, Imaging, Histopathology), Image-guided Therapy (planning, navigation, intervention), and Drug Delivery as well as Regulatory and Medical Affairs in various clinical indications especially Oncology, Cardiology and Inflammation.

Oliver was the Senior Director of Clinical Research, Strategy and Innovation with the Philips Clinical Research Board located at the Global Innovation Center, Cleveland, Ohio, from 2011 until 2018. Covering over 120 academic centers, commercial partners, international and national alliances and grant agencies in North America, Oliver led both strategy and operations, translating corporate vision into R&D and clinical roadmaps. From 2006 to 2011, Oliver was the Senior Director Bio-Molecular Engineering at Philips Research in Eindhoven, Netherlands, leading various preclinical and clinical biomarker, *in vitro* and companion diagnostics, diagnostic & interventional imaging, drug delivery and biomedical materials programs.

Prior to Philips, Oliver worked in various R&D positions at Altana Pharma AG (1999 to 2006). Major assignments were as a Head of Functional Genomics and Director of Functional Screening where he was involved in the build-up and growth of the Functional Genomics Department at German headquarters and the Altana Research Institute in Waltham, Massachusetts. Pioneering among other applications high content screening, RNAi-based technologies with underlying automation technology and bioinformatics, he managed the discovery and validation of novel pharmaceutical targets and drug candidates used in the treatment of cancer, inflammatory and gastrointestinal diseases.

Oliver received his Ph. D. in biochemistry from the University of Tuebingen and Max-Planck-Institute of Development Biology, Germany. He was awarded the Otto-Hahn-Medal of the Max-Planck Society.

Anna Moore, PhD, Co-Founder and Significant Shareholder

Dr. Anna Moore is a Professor of Radiology and Physiology; Director, Precision Health Program and Assistant Dean, College of Human Medicine at Michigan State University. Prior to joining Michigan State University, Dr. Moore was Professor of Radiology at Harvard Medical School, and the Director of the Molecular Imaging Laboratory at the Athinoula A. Martinos Center for Biomedical Imaging at Massachusetts General Hospital. Dr. Moore, a Co-Founder of TransCode, is recognized nationally and internationally for her groundbreaking research on targeted imaging and image-guided drug delivery in cancer. Her research in image-guided cancer therapy leads the field with significant advances in nucleic acid based theranostics, where technologies are developed to both diagnose and treat a variety of cancers. Dr. Moore was awarded multiple grants from the NIH and other funding agencies, and published results from these studies in the most prestigious scientific journals including Nature Medicine, Nature Protocols, Nature Photonics, Nature, Cancer Research, PNAS and others. Dr. Moore has received many awards and honors for her research, most recently a Distinguished Investigator Award from the Academy of Radiology Research in Washington, DC, and a Valkhof Visiting Professorship from Radboud University in Nijmegen, the Netherlands, both in 2014. As one of the major contributors to the field of Molecular Imaging, she was elected to be a member of the Board of Trustees of the World Molecular Imaging Society (WMIS) and a member of the Executive Committee of WMIS. She is the current Regional (US) Editor for Molecular Imaging and Biology, the official journal of WMIS. Dr. Moore holds a Ph.D. in Bioorganic Chemistry from the Russian Academy of Sciences, Moscow, Russia.

Zdravka Medarova, PhD, Co-Founder and Significant Shareholder

Zdravka Medarova, Ph.D., is an Associate Professor of Radiology at Harvard Medical School. She is a geneticist/cancer biologist by training and has an extensive background in molecular biology, genetics, and tumor biology and therapy. She developed the core nanodelivery platform and identified microRNA-10b as a promising therapeutic target in established metastases.

Specifically, the focus of her research has been the development and testing of multi-functional

imaging/delivery vehicles for combined cancer imaging and therapy. Her earliest work described, for the first time, the design and application of ultrasmall iron oxide nanoparticles as imaging-capable carriers of siRNA to tumors. More recently, her lab developed magnetic nanoparticles as delivery vehicles of miRNA-targeted therapy to metastases. This work resulted in multiple publications in high-impact journals such as Cancer Research, Nature Medicine, Oncogene, and Scientific Reports, as well as grants from private foundations and the NIH. Dr. Medarova obtained a B.A. in pre-medicine from the University of Southern Maine and a Ph.D. in Genetics from the University of New Hampshire.

| Name | Position | Age | Date Appointed | Approximate hours per week (if not full-time) | | | | | |
|--|----------|-----|------------------|---|--|--|--|--|--|
| Directors | | | | | | | | | |
| Robert Michael Dudley | Director | 68 | February 4, 2018 | | | | | | |
| Thomas A Fitzgerald | Director | 67 | July 1, 2018 | | | | | | |
| Philippe P. Calais | Director | 59 | October 7, 2018 | | | | | | |
| Executive Officers and Significant Employees | | | | | | | | | |
| Robert Michael Dudley | CEO | 68 | January 11, 2016 | Full-Time | | | | | |
| Thomas A. Fitzgerald | CFO | 67 | July 1, 2018 | 8 hours/week | | | | | |
| Oliver C. Steinbach | VP R&D | 50 | October 7, 2018 | Full-Time | | | | | |

COMPENSATION OF DIRECTORS AND EXECUTIVE OFFICERS

Since inception, we have not paid cash compensation to our executive officers, members of our board of directors, or significant employees, or, in aggregate, Named Individuals. We have provided the Named Individuals with the opportunity to purchase shares of restricted stock at fair value as of the date of issuance.

SECURITY OWNERSHIP OF MANAGEMENT AND CERTAIN SECURITYHOLDERS

The table below lists shares of our common stock held by Named Individuals, including shares that remain subject to vesting requirements. The table also shows ownership of purchasers of our Series A Preferred at the minimum and maximum offering amounts.

| Title of | Name and address of | Amount of beneficial | Percent of | Percent After \$15M | Percent After \$36M |
|-----------|--|-------------------------|------------|------------------------|------------------------|
| class | beneficial owner " | ownership | Class | Investment | Investment |
| Common | Robert Michael Dudley | 1,390,000 | 18.19% | 9.76% | 6.68% |
| Common | Anna Moore, PhD | 2,560,000 | 33.49% | 17.98% | 12.31% |
| Common | Zdravka Medarova, PhD | 2,560,000 | 33.49% | 17.98% | 12.31% |
| Common | Alan Freidman | 207,250 | 2.71% | 1.46% | 1.00% |
| Common | Thomas Fitzgerald | 210,000 | 2.75% | 1.47% | 1.01% |
| Common | Philippe Calais, PhD | 210,000 | 2.75% | 1.47% | 1.01% |
| Common | Oliver Steinbach, PhD | 82,250 | 1.08% | 0.58% | 0.40% |
| Common | All other Advisors as a group (13 individuals) | 424,000 | 5.54% | 2.98% | 2.04% |
| Preferred | Series A Investors | 3,750,000 | | 32.91% | |
| Preferred | Series A Investors | 9,000,000 | | | 43.26% |

* Address for all security holders is 6 Liberty Square, #2382, Boston MA 02109

RESTRICTED STOCK

Shares of restricted stock are common voting shares issued to advisors and board members as performance-based equity. We issued 290,000 and 304,000 shares to advisory members and board members with an aggregate value of \$29.00 and \$30.40 for the years ended December 31, 2016 and 2017.

Restricted shares generally vest over one to four years. Until August 31, 2018, the fair value of the common stock as of the date of grant was determined by the board of directors who considered, among other things, anticipated cash flows, the lack of marketability of the shares, the uncertain business prospects, current and anticipated operating losses, and the market value of equity interests in companies engaged in businesses similar to TransCode. As of November 6, 2018, the fair value of the common stock on the date of grant was determined by an independent appraisal.

TREASURY STOCK

In December 2017, we repurchased 1,689,500 shares of common stock from two former directors which shares were added to the treasury. On January 22, 2018, we issued 980,000 shares of common stock from our treasury to co-founders, and 125,000 shares to a corporate advisor. On July 1, 2018, we issued 210,000 shares of treasury stock to a Director and, on October 7, 2018, a separate 210,000 shares to another Director. On October 1, 2018, we issued 82,250 shares of treasury stock to our Vice President of Research & Development, and 82,250 additional shares to our Vice President of Investor Relations.

DESCRIPTION OF CONVERTIBLE NOTES PAYABLE

In May and June 2018, we sold \$550,000 of interest-bearing, unsecured convertible notes, or Notes, to two investors. The interest rate on the Notes is 6% per annum. Noteholders have the option to convert their notes into shares of stock in the next round of equity financing. If any of the Notes remain outstanding at such time as we consummate an equity financing, then all of the Notes, including all of the outstanding principal and accrued but unpaid interest thereon (the "Outstanding Balance"), shall be automatically converted into that number of shares of the class or series of our capital stock sold in the equity financing (the "Equity Financing Securities") as is equal to (i) the Outstanding Balance divided by (ii) the Applicable Conversion Price, defined as a twenty percent (20%) discount to the original purchase price per share of the Equity Financing Securities sold in the equity financing if the equity financing occurs less than nine months after the initial closing (the "Initial Closing") of the Notes. The discount becomes twenty-five percent (25%) if the equity financing occurs no earlier than nine months but less than eighteen months after the Initial Closing, and thirty percent (30%) if the equity financing occurs eighteen months or more after the Initial Closing. For purposes of the conversion of the Notes, an equity financing shall mean the earlier to occur of either (i) an equity investment from new or existing institutional, strategic and/or angel investors that results in aggregate gross proceeds to the Company of at least \$5,000,000 (inclusive of the aggregate gross proceeds to the Company as a result of conversion of these, or future, Notes); (ii) an equity financing in connection with which the Company and the holders of at least a majority of the aggregate principal amount of Notes

then outstanding (a "Requisite Interest") agree to convert the Notes; or (iii) an equity financing in connection with which a Noteholder elects to convert such Noteholder's Note. Unless converted, repayment of \$500,000 of these Notes is due on May 1, 2020, and repayment of \$50,000 of these Notes is due on June 26, 2020. We may issue up to \$1,500,000 in aggregate of Notes.

DESCRIPTION OF CAPITAL STOCK

GENERAL

The following description summarizes important terms of our capital stock, the rights of such stock, certain provisions of our Amended and Restated Certificate of Incorporation, our Bylaws, and certain provisions of Delaware General Corporation Law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our Amended and Restated Certificate of Incorporation, our Bylaws, applicable provisions of the Delaware General Corporation Law, and the Series A Preferred Certificate of Designation.

BOARD OF DIRECTORS

Our board of directors currently consists of three members. From time to time, our Board may grant rights to individuals to be non-voting observers at meetings of our Board.

CAPITAL STOCK

Our authorized capital stock consists of 100,000,000 shares, \$0.0001 par value per share, of which 70,000,000 shares are designated as common stock and 30,000,000 shares are designated as preferred stock. Shares of our capital stock representing approximately 20% of the total to be outstanding upon completion of the offering are intended to be reserved to meet requirements under the TransCode Therapeutics, Inc. 2019 Stock Option and Grant Plan.

PREFERRED STOCK

We have 30,000,000 shares of preferred stock authorized, of which 9,000,000 shares have been designated Series A Preferred. The Certificate of Designation of our Series A Preferred is described in our Certificate of Incorporation attached as Exhibit C, which will be filed in conjunction with the closing of this offering. Certain features of our Preferred Stock are described below. Rights of our Series A Preferred are subject to any senior class of stock that may be created in the future.

DIVIDENDS

We have never declared or paid cash dividends on our capital stock, and we do not intend to pay cash dividends on our capital stock in the foreseeable future. We intend to retain any earnings for use in the operation of our business.

In the event that our board of directors declares a dividend on our common stock, holders of our Series A Preferred are entitled to dividends in the amount per share to which the holder would have been entitled had their preferred shares been converted into common stock immediately prior to the dividend.

LIQUIDATION PREFERENCE

In the event of our voluntary or involuntary liquidation, dissolution or winding up, holders of our Series A Preferred will be entitled to receive prior to and in preference to any distributions on our common stock, an amount equal to the price per share at which the Series A Preferred shares are sold in this Offering, subject to equitable adjustment for stock splits, dividends, etc.

VOTING RIGHTS

Holders of shares of our Series A Preferred will be entitled to one vote for each share of common stock into which such preferred stock is convertible at the time of the vote. Unless otherwise required by law or our Certificate of Incorporation, the Series A Preferred will vote with our common shares as a single class.

CONVERSION

Each share of our Series A Preferred may be converted any time at the option of the holder thereof into one share of our common stock, subject to equitable adjustment for stock splits, dividends, etc.

Each outstanding share of preferred stock will be automatically converted into common stock upon the consummation of a firm commitment underwritten public offering in the US or elsewhere that results in aggregate gross proceeds to us of not less than \$25,000,000, or upon acceptance of our common shares for trading on any exchange or trading system so long as the volume-weighted average trading price per share of common stock for at least a 30-day period after such acceptance exceeds three (3) times the conversion price then in effect for our Series A Preferred.

RESTRICTIONS ON TRANSFERABILITY

The Series A Preferred Shares offered hereby will be "restricted securities" as that term is defined in Rule 144 promulgated under the Securities Act. These securities have not been registered under the Securities Act and are being offered and will be sold without benefit of registration under applicable exemptions from registration provided by federal or state securities laws. The availability of such exemptions is dependent, in part, upon the "investment intent" of purchasers of the securities. These exemptions would not be available if an investor were purchasing the shares with a view toward redistributing them. Accordingly, an investor purchasing our Series A Preferred in this offering will be required to acknowledge in the Subscription Agreement that its, his or her purchase is for investment, for its, his or her own account, and without any view to resale of the shares except pursuant to an effective registration

statement under the Securities Act, or the availability of a valid exemption from the registration requirements of the Securities Act, and subject to the terms of the Subscription Agreement.

PROTECTIVE PROVISIONS

The terms of our Series A Preferred to be sold in this offering include certain protective provisions prohibiting certain acts by us without shareholder approval, including:

- a. altering the rights of the preferred stock, except that our Board may designate future series of preferred stock without shareholder approval;
- b. reclassifying any stock outstanding at the time of the Series A Preferred original issue date as having a preference to, or to be on a parity with, the Series A Preferred as to voting rights, payment of cash dividends or liquidation preferences;
- c. repurchasing, redeeming or retiring any of our capital stock other than as required by contractual right or for nominal purchase prices;
- d. engaging in a line of business other than under a business plan approved by our Board; and
- e. entering into any transaction with an officer or director of the Company without the approval of a majority of disinterested members of our Board.

COMMON STOCK

DIVIDEND RIGHTS

Holders of our common stock are entitled to receive dividends, as may be declared from time to time by our board of directors out of legally available funds. We have never declared or paid cash dividends on our capital stock and do not anticipate paying any cash dividends after this offering or in the foreseeable future.

VOTING RIGHTS

For each share of our common stock a holder owns, they are entitled to one vote on all matters to be voted on by our stockholders.

RIGHT TO RECEIVE LIQUIDATION DISTRIBUTIONS

In the event of our liquidation, dissolution, or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after payment of all of our debts and other liabilities and satisfaction of any senior liquidation preferences that may exist.

RIGHTS AND PREFERENCES

Holders of our common stock have no preemptive, conversion, or other rights, and there are no redemptive or sinking fund provisions applicable to our common stock.

ANTI-TAKEOVER EFFECTS OF DELAWARE LAW AND OUR CERTIFICATE OF INCORPORATION AND BYLAWS

Certain provisions of Delaware General Corporation Law, our Certificate of Incorporation and our Bylaws described below could have, if invoked, 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 stockholders, 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 before the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

CERTIFICATE OF INCORPORATION AND BYLAWS

Our Certificate of Incorporation and/or Bylaws provide that:

- our Board of Directors is not "staggered" or classified into classes, so all directors are elected at each annual meeting of stockholders;
- the authorized number of directors can be changed only by resolution of our stockholders or Board of Directors;
- our Bylaws may be amended or repealed by our Board of Directors or our stockholders;
- a stockholder or stockholders may only call special meetings of the stockholders or fill vacancies on the Board of Directors if the stockholder(s) hold(s) a majority of our issued and outstanding capital stock;
- our Board of Directors will be authorized to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the Board of Directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our Board of Directors does not approve; and our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting.

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 equity offerings to raise additional capital, to facilitate corporate acquisitions or as dividend payments on our capital stock.

The existence of unissued and unreserved common 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 make 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, 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 other effects that some stockholders might consider adverse to their interests, including possibly making it more difficult for a third-party to acquire, or discouraging a third-party from acquiring, a majority of our outstanding voting stock.

PLAN OF DISTRIBUTION

We intend to offer our Series A Preferred by various means, including using an online fundraising platform. This online platform is operated by Manhattan Street Capital, or MSC, a "doing business as" activity of FundAthena, Inc. Manhattan Street Capital is not a registered broker-dealer and does not directly solicit or communicate with investors with respect to offerings posted on its site, although it does advertise the existence of its platform, which may include identifying a broad selection of issuers listed on the platform. The domain name for the online platform is https://www.manhattanstreetcapital.com/TransCode-Therapeutics.

We will pay Manhattan Street Capital for hosting our offering on its online platform. The compensation payable to Manhattan Street Capital consists of: (i) \$25 paid in cash per MSC investor when such investor funds have been deposited and accepted by TransCode (an MSC investor is defined as any person or entity that deposits money into our offering's escrow account through the MSC investment interface as part of the offering); (ii) \$5,000 per month while the offering continues; and (iii) the issuance of warrants to purchase that number of shares of our common stock as is determined by first multiplying \$25 by the total number of investors in the offering and, second, then dividing that product by the price at which our shares are sold in the offering. Compensation due to Manhattan Street Capital is not contingent upon the success of the offering.

We have not planned for sales of Series A Preferred through registered broker-dealers, but we may choose to do so. Any registered broker-dealers, or placement agents, we engage to assist with the offering shall be members of the Financial Industry Regulatory Authority. If we engage registered broker-dealers, we expect that we would pay customary compensation which may comprise cash fees, payment of certain expenses and other consideration. Participating broker-dealers or their affiliates may purchase our Series A Preferred for their own accounts. All such purchases will be included in determining whether the minimum or maximum offering amount has been achieved.

Because no trading market for our securities is expected to develop, a purchaser must be prepared to bear the economic risk of an investment in our securities for an indefinite period of time. In addition, in compliance with applicable law, our securities will be subject to transfer restrictions for one year from the expiration date of the offering.

FOREIGN REGULATORY ACTION

No action has been or is expected to be taken in any country or jurisdiction outside the United States where action is required to qualify offering our Series A Preferred, or for the possession or distribution of offering materials in connection with the offering. We will require that any registered broker-dealer we may engage to assist with the offering agrees to comply with all applicable laws and regulations in each jurisdiction in which shares of our Series A Preferred are

offered, sold or delivered or where such broker-dealer has in its possession, or distributes, any offering material, in all cases at the expense of that particular broker-dealer. No broker-dealer is authorized to make any representation or use any information in connection with the offer, issue, or sale of the Series A Preferred other than as contained in this PPM.

PROCEDURE FOR SUBSCRIBING

To consider an investment in our securities, carefully read and consider the risk factors and other information in this PPM. Investors are not to construe this PPM or any other document used in this offering, or offering documents, as constituting investment, legal or tax advice. Interested investors are urged to review the PPM, the Subscription Agreement, and other offering documents with their investment, legal, tax and other professional advisors prior to making any investment decision.

An investor should be aware that we will assert that the investor understood and accepted the risks described in this PPM or inherent in investments of this type if the investor brings a claim against us or any of our directors, officers, managers, employees, advisors, agents, or representatives.

An investor who decides to subscribe for our securities must execute and deliver to us a Subscription Agreement in the form attached hereto as Exhibit B. Subscription Agreements are not binding on us until we formally accept them. We have the right to refuse to sell our securities to any prospective investor for any reason in our sole discretion, including, without limitation, if such prospective investor does not promptly supply the information we request in connection with the subscription. In addition, in our sole discretion, we may limit the number of securities we sell to any particular investor.

In executing a Subscription Agreement, each purchaser will represent, among other things, that (a) it, he or she is acquiring the securities being purchased for its, his or her own account, for investment purposes and not with a view towards resale or distribution, and (b) immediately prior to its, his or her purchase, such purchaser satisfies the Investor Suitability Standards set forth in the PPM.

Subject to raising the minimum offering amount, one or more closings of this offering will take place in our sole discretion, each at a date, time, and place we select. It is a condition to closing of the offering that each purchaser of Series A Preferred (1) execute and deliver a Subscription Agreement and certain other documents and (2) deposit funds for the purchase of Series A Preferred into the escrow account in accordance with the instructions set forth at the MSC website. If the offering is terminated, all funds previously deposited into the escrow account will be promptly returned to subscribers without interest and without any deduction therefrom.

No purchase of any Series A Preferred Shares will be deemed to have occurred until the following conditions have been met: (i) the Subscription Agreement and related documents have been completed and delivered to and accepted by us in our sole discretion; (ii) payment in full for the purchase of the Series A Preferred has been received by us into the escrow account for the

minimum amount of the offering; and (iii) we have formally accepted all or some portion of the subscription.

Inasmuch as this offering is being made pursuant to the provisions of SEC Rule 506(c), each prospective investor will be required to provide sufficient information to enable us to verify that it, he or she is an accredited investor. We may engage a third-party to perform this verification for us. Documentation to confirm an investor's accredited status may be provided by the investor, the investor's legal counsel or the investor's accountant and may include but is not limited to W-2s, tax returns, bank and brokerage statements, credit reports, or a certification statement from the professional advisor.

The process is summarized below:

- Go to <u>https://www.manhattanstreetcapital.com/TransCode-Therapeutics</u> and click on the "Invest Now" button where the PPM, Subscription Agreement and other offering documents are available;
- 2. Complete the online investment form; the Company will perform the federally-required Anti-Money Laundering and Know Your Customer certifications (including tax number identification and legal identification verification);
- 3. Deliver the subscription payment by check, wire transfer, or electronic funds transfer via ACH to the specified account;
- 4. Complete the online accredited investor verification process; and
- 5. Electronically receive, review, execute and deliver to us your executed Subscription Agreement.

Once we accept and receive payment for the subscription, we will determine what portion, if any, of the subscription to accept, and will then complete the subscription. Pending completion of at least the minimum offering, subscription funds will be held in escrow.

No certificates evidencing the Series A Preferred Shares will be delivered to purchasers in this offering. Instead, evidence of ownership will be held in "book form" maintained by Goodwin Law with a legend thereon stating that the Series A Preferred Shares have not been registered under the Securities Act and therefore cannot be sold unless they are subsequently registered under the Securities Act or unless an exemption from registration is available.

ESCROW AGENT

MSC expects to engage Prime Trust, LLC, a registered trust company, to serve as escrow agent for the offering and to process subscription transactions.

INVESTOR SUITABILITY STANDARDS

GENERAL

An investment in our securities involves a high degree of risk and is suitable only for persons of substantial financial means who have no need for liquidity in their investment and who can bear

the economic consequences of a loss of their entire investment. Please review this entire PPM carefully, with particular attention to the section entitled "Risk Factors." Prospective investors are encouraged to consult with their financial, legal and tax advisors to determine whether this investment is appropriate for them.

Investors wishing to purchase our Series A Preferred will be required to represent that they have reviewed this PPM (including the exhibits) and that they have had the opportunity to ask questions of and receive answers from us with respect to this offering. Investors will make other representations to us in connection with purchase of the securities, including representations concerning the investor's degree of sophistication, access to information concerning the Company, and ability to bear the economic risk of the investment.

To purchase shares, a subscriber must meet one (or more) of the investor suitability standards below which must be confirmed in the Subscription Agreement. Fiduciaries purchasing shares must also meet one or more of these conditions. If the investment is a gift to a minor, the custodian or the donor must meet these conditions. We also will require each purchaser to represent and warrant in the Subscription Agreement, among other things, that he, she or it

- (1) has the ability to bear the economic risks of investing in our securities;
- (2) has, or their professional advisor has, sufficient knowledge and experience in financial, business or investment matters to evaluate the merits and risks of the investment and of protecting his, her or its interests in connection with the transaction;
- (3) is purchasing the securities for his, her or its own account, for investment only and not with a view toward the resale or distribution thereof;
- (4) is aware that the securities and the common stock underlying the securities have not been registered under the Securities Act or applicable state and foreign securities laws and that transfers of the securities are restricted by the Securities Act or applicable state securities laws;
- (5) is aware that there is no trading market for the securities nor is one expected to develop; and
- (6) meets the suitability requirements set forth below.

SUITABILITY REQUIREMENTS

Rule 501(a) of Regulation D of the Securities Act defines an "accredited investor" as any person who comes within any of the following categories, or whom the issuer reasonably believes comes within any of the following categories, at the time of the sale of the securities to that person (items 5 and 6 are those generally pertaining to individual investors):

(1) Any bank as defined in section 3(a)(2) of the Securities Act, or any savings and loan association or other institution as defined in section 3(a)(5)(A) of the Securities Act whether acting in its individual or fiduciary capacity; any broker or dealer registered pursuant to section 15 of the Exchange Act; any insurance company as defined in section 2(a)(13) of the Securities Act; any investment company registered under the Investment company Act of 1940 or a business development company as defined in section 2(a)(48) of that Act; any Small Business Investment company licensed by the U.S. Small Business Administration under section 301(c) or (d) of the Small Business Investment Act of 1958; any plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions, for the benefit of its employees, if such plan has total assets in excess of \$5,000,000; any employee benefit plan within the meaning of the Employee Retirement Income Security Act of 1974 if the investment decision is made by a plan fiduciary, as defined in section 3(21) of such act, which is either a bank, savings and loan association, insurance company, or registered investment adviser, or if the employee benefit plan has total assets in excess of \$5,000,000 or, if a self-directed plan, with investment decisions made solely by persons that are accredited investors;

(2) Any private business development company as defined in section 202(a) (22) of the Investment Advisers Act of 1940;

(3) Any organization described in section 501(c)(3) of the Internal Revenue Code, corporation, Massachusetts or similar business trust, or partnership, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of \$5,000,000;

(4) Any director, executive officer, or general partner of the issuer of the securities being offered or sold, or any director, executive officer, or general partner of a general partner of that issuer;

(5) Any natural person whose individual net worth, or joint net worth with that person's spouse, exceeds \$1,000,000;

<u>Note</u>: Net worth is the amount by which assets exceed liabilities. For purposes of calculating "net worth" under this paragraph: (i) the person's primary residence shall not be included as an asset; (ii) indebtedness that is secured by the person's primary residence, up to the estimated fair market value of the primary residence at the time of the sale of securities, shall not be included as a liability (except that if the amount of such indebtedness outstanding at the time of the sale of the securities exceeds the amount outstanding sixty (60) days before such time, other than as a result of the acquisition of the primary residence, the amount of such excess shall be included as a liability); and (iii) indebtedness that is secured by the person's primary residence in excess of the estimated fair market value of the primary residence at the time of the sale of the securities shall be included as a liability.

(6) Any natural person who had an individual income in excess of \$200,000 in each of the two most recent years or joint income with that person's spouse in excess of \$300,000 in each of those years and has a reasonable expectation of reaching the same income level in the current year;

<u>Note</u>: In determining income, a subscriber should add to the subscriber's adjusted gross income any amounts attributable to tax exempt income received, losses claimed as a limited partner in any limited partnership, deduction claimed for depletion, contribution to an IRA or Keogh plan,

alimony payments, and any amount by which income for long-term capital gains has been reduced in arriving at adjusted gross income.

(7) Any trust, with total assets in excess of \$5,000,000, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a sophisticated person as described in \$230.506(b) (2)(ii); and

(8) Any entity in which all of the equity owners are accredited investors.

In addition to the foregoing suitability standards, we cannot accept subscriptions from anyone if the representations required are either not provided or are provided but are inconsistent with our determination that the investment is suitable for the subscriber.

In addition to the financial information we require to determine suitability, the representations we require of subscribers shall state that the subscriber:

- understands that no federal or state agency has made any finding or determination as to the fairness, nor made any recommendation or endorsement, of investment our securities;
- understands that investing in our securities will not, in itself, create a qualified retirement plan as described in the Internal Revenue Code, or IRC, and that the subscriber must comply with all applicable provisions of the IRC in order to create a qualified retirement plan;
- is familiar with the risk factors we described;
- understands that there will be no public market for our securities, that there are substantial restrictions on repurchase, sale, assignment or transfer of our securities and that it may not be possible to readily liquidate an investment in our securities; and
- has investment objectives that correspond to the speculative nature of our Series A Preferred as described in this PPM.

The subscriber shall also confirm that the subscriber has the capacity to invest in our securities because:

- the subscriber is legally able to enter into a contractual relationship with us, and, if the subscriber is an individual, has attained the age of majority in the state in which the subscriber lives;
- if the subscriber is a manager of a trust on behalf of which the subscriber is purchasing our securities, that the subscriber is the manager for that trust and has due authority to purchase our securities on behalf of the trust; and
- if the subscriber is purchasing as a fiduciary, will also represent that the above representations and warranties are accurate for the person(s) for whom the subscriber is purchasing our securities.

The suitability standards referred to above represent minimum suitability requirements for prospective investors. The satisfaction of such standards by a prospective investor does not necessarily mean that our securities are a suitable investment for such prospective investor. We have the right to refuse a subscription to purchase our securities in our sole discretion even if the prospective investor meets the suitability requirements. We may make or cause to be made such

further inquiry and obtain such additional information as we deem appropriate with regard to the suitability of prospective investors. We reserve the right to modify the suitability standards and minimum investment with respect to certain investors in order to comply with applicable federal, state, local or foreign laws, regulations or otherwise.

It is anticipated that comparable suitability standards (including standards in applicable state law in particular circumstances) may be imposed by us in various jurisdictions in connection with any resale of our securities.

FEDERAL INCOME TAX CONSEQUENCES

This PPM does not address tax considerations that may be relevant to you. We urge you to consult with and rely on your own tax advisor with respect to your own federal, state and local tax situation, potential changes in applicable laws and regulations and the consequences arising from purchasing, owning and disposing of the securities. The cost of the consultation could, depending on various factors, decrease any return anticipated on your investment. Nothing in this PPM is or should be construed as legal or tax advice to any specific investor as individual circumstances vary. You should be aware that the Internal Revenue Service may not agree with all tax positions taken by us and that legislative, administrative or court decisions may reduce or eliminate any anticipated tax benefits of an investment in the securities.

EXPERTS

Our financial statements included in this PPM at Exhibit D have been audited by IndigoSpire CPA Group, LLC, independent certified public accountants, to the extent and for the periods set forth in their report appearing in the financial statements, and are included in reliance on such report given upon the authority of IndigoSpire CPA Group as experts in auditing and accounting.

RISK FACTORS

An investment in our securities involves substantial risks and uncertainties, including those that are generally associated with small companies attempting to develop new therapeutics in the biopharmaceutical industry. The risk factors described below are those we believe are more specific to our business and financial condition. In addition to the risk factors described below, we are also subject to all the same risks that all companies in the life sciences industry face, and those that all companies in the economy face as well. The latter include risks relating to economic downturns, political and economic events and technological developments (such as hacking and the ability to prevent hacking). Further, additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also materially and adversely affect us. You should consider general risks as well as specific risks when deciding whether or not to invest in our securities.

Before investing in our securities, you should fully read and carefully consider all of the information set forth in this PPM, in particular, especially, but not exclusively, the specific items in this section. The future outcome of the risks and uncertainties we face may materially and adversely affect our ability to develop and commercialize our technologies, our business, our operations, our prospects, our financial condition, our results of operations, our cash flows, and thus, the value of our securities. This is what is meant by terms "may adversely affect us," "could materially and adversely affect us" and similar expressions. You should only invest in our securities if you are able to sustain a complete loss of your investment.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

We are an early-stage, pre-clinical company with no approved products; this makes assessment of our future viability difficult to evaluate.

Investment in oncology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product- candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable.

We are unable to predict the full range of risks which may emerge, and we cannot guarantee that we will meet or achieve the clinical or commercial results we expect. The future of our business depends on us successfully developing, obtaining marketing approval for, and marketing profitably our product-candidates. This requires many complex scientific activities, successful pursuit of regulatory approvals, appropriate market assessments, the strategic management of intellectual property and financial resources, and effective management of many other aspects of our business. Any products for which we receive regulatory approval must be safe and improve patient outcomes, deliver benefits to our intended customers, be superior to competitive products and be cost effective to use. To be successful, we must also be effective in driving changes in medical and clinical practices to achieve market acceptance for our approved products and to be profitable. The risks of missteps, setbacks, errors and failings with respect to any aspect of managing our business are an inherent part of attempted innovation in the life sciences industry. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may materially and adversely affect our business.

We need the funds from the offering to strengthen our financial condition. We expect to need additional funds.

Our current cash resources are insufficient to fund our operations or development plans. If we raise less than \$15 million, we expect to be able to complete only FIM studies in a small subset of patients in only one tumor type. We may not have accurately anticipated how much we would accomplish with the funds from this offering. We may require additional funds to achieve even that objective, and, if achieved, will require additional funds to complete an adaptive trial design involving 120 patients in up to 6 different tumor types. If we are capital constrained, we may not be able to meet our obligations. If we are unable to meet our obligations, or we experience a disruption in our cash flows, it could limit or halt our ability to continue to develop our product-candidates or to even continue operations, either of which would likely have a material adverse effect on us.

Our independent public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

The report of IndigoSpire CPA Group, LLC, our independent public accounting firm, on our financial statements for the fiscal year ended December 31, 2017, and for the period from January 11, 2016, (inception) through December 31, 2016, contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles. IndigoSpire CPA Group's report expressed substantial doubt about our ability to continue as a going concern. Such doubts were based on our recurring net losses, accumulated deficit and working capital deficiency resulting from insufficient cash. Our ability to continue as a going concern is subject to our ability to generate profits or obtain funding from outside sources, including sales of capital stock or debt or from other financing arrangements. Our efforts to continue as a going concern may not prove successful even if we obtain funding in this offering or otherwise.

We have a limited history, have incurred losses since inception, and expect to continue to incur substantial losses for the foreseeable future. We may never achieve profitability or sustain it if achieved.

We were established January 11, 2016. As a result, investors do not have access to the same type of information in assessing their proposed investment as would be available to purchasers in a company with a long history of operations. We face all the risks inherent in a new business, including the expenses, difficulties, complications and delays frequently encountered in connection with conducting operations, including capital requirements and management's potential underestimation of initial and ongoing costs. We also face the risk that we may not be able to effectively implement our business plan. If we are not effective in addressing these risks, we will not operate profitably and we may not have adequate working capital to meet our obligations as they become due

Since inception, we have incurred operating losses. We had an accumulated deficit of approximately \$188 thousand at September 30, 2018. We have not commercialized any products or generated revenues from product sales or otherwise. We do not expect to generate revenues in the foreseeable future. We do not know whether or when we will generate product revenues or become profitable, if ever. If we achieve profitability, we may not sustain it.

We have devoted most of our resources, human and financial, to development of the company and related activities including preparing for this offering. We have financed our operations primarily through private sales of debt securities. We anticipate that our expenses will increase significantly after the offering as we continue development of our product-candidates, complete pre-clinical development, plan for and conduct clinical trials, seek regulatory approvals for our product-candidates, begin and continue manufacturing ourselves or through contracted arrangements, and enter and pursue commercialization of approved products either directly, indirectly such as through partnerships or distributors, or by some combination of direct and indirect. We expect to hire clinical, scientific, marketing and administrative personnel or to outsource these functions. We expect to need to implement internal management systems and corporate infrastructure to administer and operate our company. All of these activities will materially increase the rate and amount of our spending and contribute to future losses.

We have not completed any clinical studies for our lead product-candidate, TTX-MC138, and we expect it will be years, if ever, before we have a product-candidate ready for commercialization. Even if we obtain regulatory approval to market a product-candidate, our future revenues will depend upon the size of the markets for our approved products, market dynamics at the time of commercialization, our ability to achieve sufficient market acceptance and numerous other factors.

Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we cannot accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve profitability. Regulators may require that we perform studies in addition to those we expect. If we encounter unforeseen issues in developing our product-candidates, or if there are any delays or set-backs in completing clinical trials or development activities, our expenses could increase, which could materially and adversely affect us. To become and remain profitable, we must succeed in, among other things, developing and eventually commercializing products that generate significant revenue. This will require us to successfully manage a range of challenging activities, including completing pre-clinical studies and clinical trials with our product-candidates, obtaining regulatory approval to market these product-candidates, and manufacturing, marketing and selling profitably any products for which we obtain regulatory approval. We may never succeed in these efforts and, even if we do, we may never generate revenues significant enough to achieve profitability.

If we do achieve profitability, we may not be able to sustain it on a quarterly, annual or any basis. Our failure to become or remain profitable would likely depress the value of our securities and could impair our ability to raise capital, expand our business, maintain our research and development efforts, expand our product offerings, or even continue operations. A decline in the value of our securities could result in a loss of part or all of your investment.

Preparing financial projections and forecasts involves uncertainties and contingencies.

Because we are unable to predict the full range of risks we may encounter as we develop our product-candidates and market products for which we obtain marketing approval, we cannot guarantee that we will achieve our financial projections. In preparing financial projections, we make assumptions and use estimates regarding many factors, including the time and costs required to develop and obtain regulatory approval for our product-candidates, future

manufacturing costs, and future market factors and conditions, any of which may change or prove materially different than we estimated or assumed. Any material change in these assumptions or difference from our expectations could adversely affect us.

Because our product-candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products or generating product revenues.

Our product-candidates are development stage technologies which require more, complex future development as well as regulatory approval prior to commercialization. It is impossible to fully mitigate the risks associated with bringing forward new technology and developing product-candidates. These product-candidates may fail at any point in development or in clinical trials.

Therefore, there is no assurance that any of our product-candidates will be successfully developed, be approved or cleared for sale by regulators, be accepted in the market or be profitable. Any delay or setback in the development of a product-candidate could materially adversely affect us.

In addition to development risks, we also face the risk that existing or evolving drug regulations may create barriers to licensure that we are unable to overcome, making it impossible for us to license any product we develop. Our product-candidates may fail in clinical trials. We may never achieve the product claims necessary to successfully launch any products commercially. We may not succeed in changing the practice of medicine such that our products are adopted as we anticipate. The data we generate in our clinical programs may not be viewed by physicians as strong enough for them to use and by third-party payers as effective enough for them to reimburse the cost of our products. Further, changes in the practice of medicine may render our approved products obsolete.

We also face the risk of:

- competitors introducing technologies which render our development efforts or approved products obsolete;
- data from our clinical trials not being strong enough to support the marketing claims needed for market success and to achieve our financial projections; and
- being unable to manufacture or supply, or have manufactured or supplied on our behalf, approved products cost-effectively.

Our business is highly dependent on the success of TTX-MC138, currently our only developed therapeutic product-candidate, which is at the early stages of development.

If we are unable to successfully develop, obtain regulatory approval for and commercialize TTX-MC138, or experience significant delays in doing so, our business will be materially harmed. Advancing TTX-MC138 will require substantial investment before we can seek regulatory approval and potentially launch commercial sales. Further development of TTX-MC138 will require additional pre-clinical work, clinical studies, regulatory review and approval in the U.S. and in other jurisdictions, development of sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales, if approved.

In developing TTX-MC138, among other risks, we may not be successful in synthesizing or producing the components of our proprietary formulation, or there may be toxicology issues from key components of our formulation which we have not anticipated. We have not tested TTX-MC138 using the production processes, equipment and materials most frequently used in our major target markets.

We are early in our development efforts. TTX-MC138 is in pre-clinical development and has yet to be tested in humans. If we are unable to successfully move to clinical development and develop and commercialize TTX-MC138 or other product-candidates, or we experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have only one therapeutic candidate in preclinical development. We need to conduct significant additional research and testing, and must obtain authorizations and approvals prior to beginning any clinical studies. Significant delays in starting, or the inability to begin, clinical trials will jeopardize our ability to develop a viable product and will materially harm our business.

If clinical trials of TTX-MC138 fail to demonstrate safety and efficacy, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TTX-MC138.

Clinical trials are required to apply for regulatory approval to market TTX-MC138. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. We do not know whether any clinical trials we begin will continue as planned, will need to be restructured or will be completed on schedule or at all. Significant clinical trial delays also could allow competitors to bring products to market before we do and could impair our ability to successfully commercialize our product-candidates, any of which could materially harm our business.

We could also experience significant delays for any number of reasons including slow approvals by regulators or our failures to complete pre-clinical testing in a timely manner. A failure of a clinical trial can occur at any stage. Most product-candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We cannot guarantee that we will be successful in obtaining approvals to begin or continue clinical trials or that any trials we conduct will demonstrate that our product-candidates are safe or effective. Any of the foregoing could result in higher costs which could materially harm our business.

If we fail to obtain needed capital, we may be unable to complete development and commercialization of TTX-MC138.

We expect to continue to require substantial capital to further advance TTX-MC138 in clinical development, to scale-up manufacturing, to acquire or in-license other drugs and technologies, to seek regulatory approvals, possibly to establish a commercial sales force and to manufacture and market products, if any, that are approved for commercial sale.

Our commercial revenues, if any, will be derived from sales of our therapeutic, if approved, which we do not expect for several years, if at all. Accordingly, we will need to continue to rely on additional financing to fund our business. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital

and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of TTX-MC138, other research and development initiatives or even all our operations.

Our failure to obtain the capital we need could impair our ability to achieve our business objectives, maintain our research and development efforts, expand our business and our product offerings, or even continue operations. Any of the foregoing could materially harm our business and could result in a loss of part or all of your investment.

Quality problems could delay or prevent delivery of our products to the market.

Quality is important due to (i) the serious and costly consequences of process or product failure and (ii) it being one required element of the regulatory approval process. Receiving quality certifications is critical to the development and marketing success of our technologies. If we fail to meet existing or future quality standards, development or commercialization of our technologies could be materially and adversely affected.

We are required to comply with part 820 in Title 21 of the Code of Federal Regulations, or CFR, and the FDA Quality Systems Regulations to manufacture products anywhere in the world for sale in the U.S.

Also, the International Standards Organization, or ISO, sets quality standards that are widely accepted and applied around the world, including in the U.S. We are also subject to ISO 13485 and ISO 9000 standards. It is the most commonly applied standard whereby medical products companies demonstrate that their products meet quality system requirements established for Europe, Canada, Japan, Australia and other countries. The requirements of ISO 13485 cover process control, design control, retention of records, accountability, traceability, customer feedback, and other areas. We will be required to be certified under ISO 13485 to sell our products in Europe and other international markets. Implementing ISO 13485 is voluntary for manufacturers selling in the United States.

We will need to implement a quality system designed to meet the requirement to sell our approved products in both the U.S. and Europe. We cannot guarantee that our development standards, processes and procedures will meet applicable requirements for regulatory approval in any jurisdiction or that they will mitigate all of the risks associated with the development and commercialization of our product-candidates. Even if we receive quality certifications, we could subsequently lose them or be required to take corrective actions if we do not continue to meet, implement and follow the requirements under the applicable standards. If we fail to meet quality requirements applicable to our product-candidates and approved products, it could have a material adverse effect on us.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The number of qualified clinical trial investigators and sites is limited. We expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use. This could reduce the number of patients available for our clinical trials at such clinical trial site. Clinical trials of other companies may be in similar therapeutic areas as ours. This competition will reduce the number and types of patients and qualified clinical investigators available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a competitor or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there.

We may also encounter difficulties finding a clinical trial site at which to conduct our trials. Because TTX-MC138 represents a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, radiation and monoclonal antibodies, rather than enroll patients in any of our clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our therapeutic or any other future versions of it.

RISKS RELATED TO THIRD PARTIES AND SUPPLIERS

We expect to rely on third-party manufacturers which may cause supplies of materials for research and development, pre-clinical and clinical development to become limited or interrupted or which may fail to meet our quantity, quality or costs requirements.

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of TTX-MC138 and any future potential product-candidates that we may develop.

We may be unable to establish additional agreements, or extend existing agreements, with thirdparty manufacturers or to do so on terms acceptable to us. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third-party for sufficient quantity and quality at acceptable costs which could delay, prevent or impair our development or commercialization efforts;
- the possible breach of the manufacturing agreement by the third-party;
- failure to meet our manufacturing specifications;
- failure to meet our manufacturing schedule;
- misappropriation of our proprietary information, including our trade secrets and knowhow;
- the possible termination or nonrenewal of the agreement by the third-party at a time that is costly or inconvenient for us;
- disruptions to the operations of our manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of a manufacturer or supplier; and
- reliance on the third-party for regulatory compliance, quality assurance and safety reporting.

Our reliance on others for our manufacturing will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all applicable regulations regarding manufacturing. Our product-candidates and any products that we may develop may compete for access to manufacturing facilities with other product-candidates and products. There are a limited number of manufacturers that operate in accordance with cGMP regulations that might be capable of manufacturing for us which could restrict our ability to supply products and, as a result, have a material adverse effect on us.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or could otherwise adversely affect our ability to commercialize our approved products. Some of these events could be the basis for costly FDA action, including injunction, recall, seizure or total or partial suspension of production.

We will have limited control over the day-to-day manufacturing and quality operations of our contract manufacturers. While we will exercise commercially reasonable efforts to oversee operations and embed our quality system standards and controls in our manufacturing agreements, we will remain subject to the performance of our contract manufacturers. We must depend on our suppliers for proper oversight and control of their operations. Our outside manufacturers may themselves rely on other parties that they do not control. Our suppliers might fail to obtain, or experience delays in obtaining, regulatory approvals applicable to the aspects of their business that pertains to us. As a result, the development and commercialization of our products may be delayed. If this occurs, we may need to identify alternative sources of supply which may not be feasible or which may adversely affect our timelines and financial results.

Our dependence upon others for the manufacture of our product-candidates or products may adversely affect our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Thus, our current and anticipated future dependence upon others for manufacturing may adversely affect our timelines, our future profit margins or our ability to commercialize any product-candidates that receive marketing approval on a timely and competitive basis.

Any part of our supply chain could be disrupted or our suppliers might not perform as we anticipate.

Issues with key suppliers could impact the manufacture of our product-candidates or products or our ability to obtain key components or raw materials. Certain key products and components will be manufactured at single locations, and our ability to find alternate or replacement suppliers in a short period of time will be limited. If an event occurs that results in damage to one or more of these facilities, we may be unable to manufacture our products which could adversely affect our ability to commercialize our products as projected. A reduction or interruption in manufacturing, or our inability to secure alternative sources of raw materials or components, could have a material adverse effect on our ability to finalize development, launch our products and achieve our projected financial results.

Parties conducting some or all of our product manufacturing may not perform satisfactorily.

Outside manufacturers may not be able to or may not comply with cGMP regulations or similar regulatory requirements outside the U.S. Our failure, or the failure of our manufacturers, to comply with applicable regulations could delay clinical development or marketing approval or result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product-candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

We may not have arrangements for redundant supply or a second source for key materials, components or our products and product-candidates. If our contract manufacturers cannot perform as expected, we may be required to replace such manufacturers. There may be only a small number of potential alternative manufacturers who could manufacture our product-candidates. We may incur added costs and delays in identifying, gaining access to and qualifying any such replacement.

We are highly dependent on others to provide services for certain core aspects of our business.

To conserve financial resources, we utilize consultants, advisors and other parties for certain functions including regulatory affairs, clinical trials, medical practice issues, product management and human resources. If other parties are not available to provide services through completion of our programs at the times we require their services, or if the expertise we require is not readily available, the development and commercialization of our product-candidates may be delayed.

Our product-candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable side effects caused by any of our product-candidates could cause us, IRBs, our CROs, the FDA or other regulatory authorities to interrupt, delay or discontinue clinical trials and could result in the denial of regulatory approval for our product-candidates. This, in turn, could prevent us from commercializing our product-candidates and generating revenues from their sale.

Also, any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from becoming profitable.

Users of any of our products that reach the market and their customers might not obtain adequate reimbursement from governmental or other third-party payors for the costs of our products.

Although cancer therapeutics are generally reimbursed or otherwise provided for in our target markets, the increasing pressure of rising healthcare costs around the world, including more restrictive national healthcare plans and plan changes by payors, may result in tightened reimbursement policies which could adversely and materially affect us. There is no assurance that payors in any market will provide for reimbursement of any approved products we commercialize.

We face significant competition.

The biopharmaceutical marketplace is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies. Most of our competitors have substantially greater capital and other resources than we do, have established positions in the marketplace, and have established relationships with clinical investigators and other parties that could prevent or delay our development and require that we spend significantly more than we plan to meet our objectives.

Not only must we compete with other companies that are focused on therapeutics that treat cancer, but also any product-candidates that we successfully develop and commercialize will compete with existing and new therapies that may become available in the future. Our competitors may develop more successful products similar to ours sooner than we can commercialize ours, which may negatively impact our results.

We currently have no marketing and sales organization and have no experience in selling, marketing or distributing therapeutic products. If we are unable to establish marketing and sales capabilities or enter into agreements with third-parties to market and sell our products, we may not be able to generate revenues from sales of approved products.

We have no sales, marketing or distribution capabilities and have no experience marketing therapeutics to treat patients with cancer. If one of our therapeutic-candidates is approved for sale, we intend to either license it to a larger pharmaceutical company with a sales force or develop our own marketing organization and sales force. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third-parties, we will not be successful in commercializing our product-candidates and our product revenues and profitability, if any, may be materially and adversely affected.

If we license our product to a third-party, we will be subject to the risks of that type of collaborative arrangement, including dependence on a third-party for our commercial results. There is no assurance that any party will enter into an arrangement with us. If we enter into one or more arrangements, the terms of those arrangements may not be as favorable to us as we would like. Parties with which we enter into arrangements may not perform as we expect. We likely will have little control over such parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. These and other risks may materially and adversely affect our commercial success.

There are risks involved with establishing our own capabilities. Developing our own in-house capabilities will require significant capital resources, management personnel and time. Recruiting and training a sales force is expensive and time consuming. If we mismanage this process, it could delay a product launch. If we establish our own capabilities and the commercial launch of our product-candidates is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These costs may be material, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Other factors that may inhibit our efforts to commercialize our products 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 oncology centers and hospitals and physicians;
- the lack of adequate numbers of physicians prescribing our approved products;
- the lack of complementary products that can be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs, expenses and problems associated with creating a sales, marketing and distribution capability.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

A part of our strategy is to seek, evaluate and, when strategically attractive, enter into development and commercial partnerships. Potential partners may include larger medical products companies. These potential partners often have their own internal development programs and priorities which may be a potential source of competition for our product-candidates. We must develop technologies of value and then demonstrate the value of our technologies and product-candidates if we are to be successful in arranging strategic partnerships on terms that will be attractive. There are no assurances that we will succeed in arranging any partnerships.

Identifying appropriate partners for our product-candidates and the negotiation process is lengthy, time-consuming and complex and we have limited resources to do this. In order for us to successfully partner our product-candidates, potential partners must view these productcandidates as economically and technologically valuable with features or benefits that are superior to existing products or product-candidates in development. We may not be able to maintain such strategic partnerships if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our product-candidates could delay their development and commercialization and reduce their competitiveness even if they reach the market.

In addition, strategic partners may not perform as we expect or may breach their agreements with us. We may not be able to adequately protect our rights under these agreements and attempting to do so is likely to be time consuming and expensive. Furthermore, our strategic partners will likely seek to control certain decisions regarding the development and commercialization of our product-candidates and may not conduct those activities in the manner or time we would like.

If we fail to establish and maintain strategic partnerships related to our product-candidates, we will bear all of the risk and costs related to the development and commercialization of our product-candidates. This may require us to seek additional financing, hire additional employees and otherwise develop expertise which we do not have. These factors could materially and adversely affect the development or commercial success of any product-candidate for which we do not arrange a strategic partnership.

Sales of our products may involve a lengthy sales cycle.
Many factors are expected to influence the sales cycle for our approved products. These factors include the future state of the market, the perceived value of our product-candidates, the evolution of competing technologies, and changes in medical practices. Any of these may adversely affect our sales cycles and the rate of market acceptance of our approved products.

We are dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may fail to successfully implement our business strategy.

Our ability to compete in the highly competitive oncology industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are dependent on our management, scientific and medical personnel and advisors, including our co-founder and CEO, Michael Dudley, our CFO, Tom Fitzgerald, our head of R&D, Dr. Oliver Steinbach, and our scientific co-founders, Dr. Zdravka Medarova and Dr. Anna Moore, our board of directors and members of our scientific and business advisory boards as well as our many consultants. The loss of the services of any of these individuals, and our inability to find suitable replacements, could result in delays in product development and materially harm our business.

REGULATORY RISKS

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product-candidates, including:

- regulators or institutional review boards, or IRBs, not authorizing us or our investigators to initiate a clinical trial or conduct a clinical trial at a prospective trial site;
- government or regulatory delays and changes in regulatory requirements, policy and guidelines;
- delays in reaching or failure to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and contract research organizations (CROs), or failure by such CROs or trials sites to carry out the clinical trial in accordance with the terms of our agreements with them;
- CMC or manufacturing issues with either contract manufacturer when inspected may create problems or delays, lead to clinical hold for safety reasons, or cause significant delays due to inability to consistently provide study product;
- negative or inconclusive results of clinical trials;
- a decision by us to conduct additional clinical trials or abandon product development programs;
- a higher number of patients required for clinical trials, slower than expected enrollment, greater than expected competition for patients or higher than expected drop out rates;
- unexpected benefits measured from the active comparator arm or placebo arm;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- failure of third-party contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;
- suspension or termination of clinical trials for various reasons, including unacceptable health risks;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or site by the FDA or other regulatory authorities;
- greater than expected cost of clinical trials;
- insufficient supply or quality of product-candidates or other materials necessary to conduct clinical trials;
- undesirable side effects or other unexpected characteristics of our product-candidates, causing us or our investigators, regulators or IRBs to suspend or terminate the trials; and
- revision of legal or regulatory requirements for approving therapeutic.

If we are required to conduct additional clinical trials or other testing beyond what we currently contemplate, if we are unable to successfully complete clinical trials or other testing of our product-candidate, if the results of our trials or tests are not positive or are only moderately positive, or if there are any safety concerns, we may:

- be delayed in obtaining marketing approval for our therapeutic;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval but with labelling having significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market even after obtaining marketing approval.

The timely completion of clinical trials depends on, among other things, our ability to enroll a sufficient number of patients who complete the trial. The enrollment of clinical trial subjects depends on many factors, including:

- the number of clinical trials for other product-candidates in the same or similar therapeutic areas in clinical development at the same time, and our ability to compete for clinical trial subjects and sites;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population;
- the risk that disease progression will result in death before the patient can enroll in our clinical trial or before completion of the clinical trial in which the subject is enrolled;
- the proximity and convenience of clinical trial sites to prospective subjects;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain clinical trial subjects' consents; and
- the risk that subjects enrolled in our clinical trial will drop out before completion.

RISKS RELATED TO GOVERNMENT REGULATION

We may be unable to obtain U.S. or foreign regulatory approval of TTX-MC138 and, as a result, we may be unable to commercialize our product-candidate.

Our lead product-candidate, TTX-MC138, is, and any future product-candidates that we may develop will be, subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing, distribution, import and export of drugs. Rigorous preclinical testing and clinical trials, and an extensive regulatory approval process, are required before a new drug can be marketed in the United States and in many foreign jurisdictions. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product-candidates we may develop will obtain the regulatory approvals necessary for us or our collaborators to commercialize them.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product-candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product-candidates will be materially harmed.

Even if we receive regulatory approval of TTX-MC138, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product-candidates.

Any regulatory approvals that we receive for TTX-MC138 or another product-candidate may require post-marketing surveillance to monitor the safety and efficacy of the product, and may require us to conduct post-approval clinical studies. The FDA may also require a REMS in order to approve our product-candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product-candidates, the manufacturing processes, labeling, packaging, distribution, Adverse Event reporting, storage, advertising, promotion, import, export and recordkeeping for our product-candidates will be subject to extensive and ongoing regulatory requirements. These requirements can include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Compliance with ongoing and changing requirements takes substantial resources and, should we be unable to remain in compliance, our business could be materially and adversely affected.

If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, we or they

could be subject to enforcement actions, which could result in penalties, adversely affect our ability to develop, market and sell our approved products, and harm our reputation.

If our operations are found to be in violation of healthcare laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could materially and adversely affect our business. Although effective compliance programs can mitigate these risks to a degree, they cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations is costly in terms of money, time and resources.

Obtaining and maintaining regulatory approval for our product-candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that or of any of our other product-candidates in other jurisdictions.

Obtaining and maintaining regulatory approval for TTX-MC138 in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for TTX-MC138, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product-candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as preclinical studies and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product-candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we charge for our product is also subject to regulatory approval.

Our products may be subject to recalls even after receiving regulatory clearance or approval.

We will be required to continually monitor the safety of any approved products for signs of manufacturing problems or evidence that their use elicits serious or unexpected side effects or adverse events, the occurrence of which could jeopardize our ability to continue marketing the product. In the case of recalls or product safety issues, we may incur substantial costs, including from product liability losses, or become subject to other lawsuits. Our potential product or other liability exposure is far in excess of our limited insurance coverage. We might incur substantial liabilities and could be required to change, limit or cease operations or the commercialization of our products.

RISKS RELATED TO OTHER GOVERNMENT REGULATIONS

Our current and potential future business activities and operations, and our relationships with health care professionals, institutional health care providers, principal investigators, consultants and potential customers are, or will be, subject, directly and indirectly, to federal, state, local and foreign laws and regulations. We may be particularly affected by healthcare laws and regulations relating to fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and health information privacy and security laws. If we are unable to comply, or do not fully comply, with applicable laws or regulations, we could face material penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, contractual damages, reputational harm, curtailment or restructuring of our operations, or other repercussions, any of which could materially adversely affect us.

Depending on decisions we may make regarding our business operations and activities and other factors, we may be directly or indirectly subject to or affected by various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. If we obtain FDA approval for any of our product-candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly. Our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current or future activities with collaborators, clinical investigators and research subjects, as well as future sales, marketing and education programs. In addition, we may be subject to patient privacy laws and regulations.

The laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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 a federal health care program, such as the Medicare and Medicaid programs;
- the federal Physician Payments Sunshine Act, created under Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, ACA, and its implementing regulations. ACA requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the U.S. Foreign Corrupt Practices Act which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and
- state laws and the laws of other jurisdictions comparable to U.S. federal laws, including those above, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as claims submitted

involving health care items or services reimbursed by any third-party payor, including commercial insurers; laws that require medical product companies to comply with voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government that otherwise restricts payments that may be made to health care providers; laws that require drug manufacturers to file reports regarding marketing information, such as the tracking and reporting of gifts, compensation and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative effect on our business and/or increase enforcement scrutiny of our activities); and laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

Efforts to ensure that our business arrangements comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

RISKS RELATED TO MARKET CONDITIONS

Healthcare reform in the U.S. and other countries may materially and adversely affect us. In the U.S. and in many foreign jurisdictions, the legislative landscape continues to evolve. Our revenue prospects could be affected by changes in healthcare spending and policies in our target markets. We operate in a highly regulated industry and new laws or judicial decisions, or new interpretations of existing laws or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could materially and adversely affect us.

There is significant interest in promoting healthcare reform, as evidenced by the enactment in the U.S. of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act in 2010, or together, the ACA. It is likely that many governments will continue to consider new healthcare legislation or changes to existing legislation. We cannot predict the initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified, or how they may affect us. The continuing efforts of governments, insurance companies, managed care organizations and other third-party payors to contain or reduce healthcare costs may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;

- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Under the ACA, there are many programs and requirements for which details or consequences are still not fully understood. We are unable to predict what healthcare programs and regulations will ultimately be implemented at any level of government in or outside the U.S., but any changes that decrease reimbursement for our approved products, reduce volumes of medical procedures or impose new cost-containment measures could adversely affect us.

ADVERSE MARKET AND ECONOMIC CONDITIONS MAY EXACERBATE CERTAIN RISKS AFFECTING OUR BUSINESS.

The healthcare market is undergoing significant change, presenting new challenges for market participants, their business models and their hospital customers. There is increasing pressure to reduce costs throughout the healthcare system. Consolidation of healthcare providers has resulted in increased pressure for price concessions from product suppliers.

As a result of these and other market forces and conditions that we cannot predict, the introduction of new technologies may face higher hurdles and increased time to adoption as hospitals and payors adjust to market changes and more closely assess the costs and benefits of new products.

We are subject to geopolitical risks, economic volatility, anti-corruption laws, export and import restrictions, local regulatory authorities and the laws and medical practices in foreign jurisdictions.

The costs of healthcare internationally have risen significantly over the past decade. Numerous initiatives and reform by legislators, regulators and third-party payers to curb these costs have reduced reimbursement rates. One outcome of these dynamics is that hospitals and others are consolidating into larger integrated delivery networks and group purchasing organizations in an effort to reduce administrative costs and increase purchasing power. This consolidation has resulted in greater pricing pressure on suppliers, decreased average selling prices and changes in medical practices. If we secure marketing approval for our product-candidates, our commercial success will be determined by, among other things, our ability to obtain acceptable pricing for approved products which will be subject to, among other things, the factors described above.

The expansion of group purchasing organizations, integrated delivery networks and large single accounts among hospitals could also put price pressure on our approved products. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors. The result may be further downward pressure on the prices we are able to obtain, thus adversely affecting us.

RISKS RELATED TO INTELLECTUAL PROPERTY

The patent covering TTX-MC138 is issued only in the U.S. currently and there are no foreign applications pending for this invention. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product-candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or other jurisdictions. Competitors may use our 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 have patent protection, but enforcement is not as strong as that in the United States. These products may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign 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, particularly those relating to oncology products, 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 foreign jurisdictions 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.

If we are not able to obtain and enforce patent and other intellectual property protection for our technologies, development and commercialization of our product-candidates may be adversely affected and our business materially harmed.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licensing intellectual property rights of others, for our product-candidates, methods used to manufacture our product-candidates and methods for treating patients using our product-candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing our proprietary rights and to operate without infringing the proprietary rights of others. We have filed and expect to file additional patent applications related to various aspects of TTX-MC138 and our other possible future drug product-candidates. If issued, certain patents may require us to obtain a license from MGH.

We and our current or future licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our technologies at reasonable cost, in a timely fashion, or at all. The patent position of oncology companies can be highly uncertain because it involves complex

legal and factual questions. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable, or that any issued or granted patents will include claims that are sufficiently broad to cover our product-candidates or delivery technologies or provide meaningful protection from our competitors. If third-parties disclose or misappropriate our proprietary rights, it may materially and adversely affect us.

While we will endeavor to try to protect our technologies with intellectual property rights such as patents, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable. The U.S. Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the process of pursuing patent coverage. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than otherwise would have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in oncology patents. Moreover, changes in either the patent laws or in the interpretations of patent laws may diminish the value of our intellectual property. As such, we do not know the degree of future protection that we might have with respect to our proprietary technologies. Further, patents have a limited lifespan.

In the United States and in industrialized countries generally, a patent expires 20 years after it is filed (or 20 years after the filing date of the first non- provisional US patent application to which it claims priority). Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our technologies, we may be more susceptible to competition, including from generic versions of our product-candidates. Further, the extensive period of time between patent filing and regulatory approval for a product-candidate limits the time during which we can market a product-candidate under patent protection, which may particularly and adversely affect our profitability.

We or any future strategic partners may become subject to third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights.

We or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. If we, our licensors or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay substantial damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. In addition, we, our licensors or any future strategic partners may choose to seek, or be required to seek, a license to technology owned by a third-party, which license may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be limited which could give our competitors access to the same technology or intellectual property rights as is licensed to us. If we fail to obtain a required license, we may be unable to effectively market certain approved products which could materially harm us. Alternatively, we may need to redesign our infringing products, which may

be impossible or require substantial time and monetary expenditure. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in litigation or other proceedings relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and would divert our management's attention from operating the business. Most of our competitors would be better able to sustain the costs of complex patent litigation than us because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could materially delay our research and development efforts and significantly limit our ability to continue our operations.

We may not be able to protect our intellectual property.

Our profitability may depend in part on our ability to effectively protect our proprietary rights, including obtaining patent protection for our methods of manufacturing our products, maintaining the confidentiality of our trade secrets, as well as our ability to operate without inadvertently infringing the proprietary rights of others. There can be no assurance that we will be able to obtain patents or defend our current and future patents. Further, policing and protecting our intellectual property against unauthorized use by third-parties is time-consuming and expensive, and certain countries may not even recognize our intellectual property rights. There is also no assurance that a third-party will not assert patent infringement claims with respect to our products or technologies. Any litigation for either protecting our intellectually property or defending our use of certain technologies could have a material adverse effect on our business, regardless of the outcome of such litigation.

Confidentiality agreements with employees and others may not prevent unauthorized disclosure of proprietary information.

Among the ways we attempt to protect our intellectual property is by entering into confidentiality agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are intended to protect (i) proprietary know-how that may not be patentable or that we may elect not to patent, (ii) processes for which patents are difficult to enforce and (iii) other elements of our technology not covered by patents. Although we use reasonable efforts to protect our intellectual property, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our intellectual property to competitors or others. In addition, competitors may otherwise gain access to our intellectual property or independently develop substantially equivalent information and techniques. Enforcing a claim that another party illegally obtained and is using any of our intellectual property. Misappropriation or unauthorized disclosure of our intellectual property could materially and adversely affect our competitive position and may have a material adverse effect on us.

RISKS RELATED TO THE OFFERING

If we do not raise sufficient funds, we will not succeed.

Our offering is for a minimum of \$15 million and a maximum of \$36 million. If we raise only the minimum amount of funds sought, we will have to find other sources of funding. Regardless of how much capital we raise, it may not prove sufficient to achieve our objectives. Additional

capital in the future, if obtained at all, may be obtained at a lower valuation, which would dilute the interest of investors in this offering, or on more favorable terms – for example, debt financing, which could be positioned ahead of the investors in this offering in terms of seniority.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from the offering, including for any of the purposes described in "Use of Proceeds." You will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used effectively. Because of the number and variability of factors that will determine our use of the net proceeds, their ultimate use may differ substantially from what we currently intend. The failure by our management to apply these funds effectively could adversely affect us. Pending their use, we may invest the net proceeds in short-term, investment-grade, interest-bearing securities or commercial bank accounts. While we intend to invest the net proceeds conservatively, there is no assurance that these investments will not decline in value or yield reasonable returns.

There is no trading market for any of our securities nor is any expected to develop.

There is no trading market for resales of our securities. We will not be registering the Series A Preferred or the common stock into which the Series A converts, so they will be illiquid and there is not expected to be any trading market for the foreseeable future. Investors should assume that they may not be able to liquidate their investment for some time, if ever, or be able to liquidate their shares in other ways.

The purchase price for the shares has been arbitrarily determined.

The purchase price for the securities we set has been determined arbitrarily and bears no relationship to our assets, book value, earnings or other generally accepted criteria of value. In determining this price, we considered factors such as our limited financial resources, the nature of our assets, our estimates of our business potential, our estimates of the cash required to attain certain objectives, the valuation of certain other life sciences companies, and general market and economic conditions. Furthermore, unlike listed companies whose stocks are valued by market activity, the valuation of private companies, especially startups, is difficult to assess. You risk overpaying for your investment even if we achieve our objectives.

If you purchase securities in this Offering, you will incur immediate and substantial dilution in the book value of the shares into which your securities are convertible.

If you invest in our securities in this offering, the book value of your ownership interest will be diluted immediately to the extent of the difference between the effective offering price per share of our common stock into which your securities are convertible and the *pro forma* net tangible book value per share of our common stock after this offering.

Raising additional funds through debt or equity financing could be dilutive and may cause the value of our securities to decline.

Until such time, if ever, as we can generate the cash we need from operations, we expect to attempt to finance our cash needs through equity and debt financings, and potentially through license and development agreements with strategic partnerships with third parties. Raising

additional capital through the sale of equity or debt securities convertible into or involving equity such as through warrants, could result in substantial dilution for our then current stockholders. Also, the terms of those transactions may include liquidation or other preferences that are senior to the rights of our then current stockholders. Then existing stockholders may not agree with our financing plans or the terms of such financings and may deem such financings adverse to their interests. Moreover, incurring debt could result in a substantial portion of our operating cash flow being dedicated to the payment of principal and interest on such indebtedness and could impose restrictions on our operations, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely affect our ability to conduct our business. Additional funding may not be available to us on acceptable terms, or at all.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, to repay our indebtedness when due (causing a default under such indebtedness), which could have a material adverse effect on us.

Future issuances of our capital stock or rights to purchase our capital stock, including pursuant to equity incentive plans, could result in additional dilution.

To the extent we issue shares of our capital stock in the future, for example, to raise additional capital or in connection with equity incentive plans, the proportionate interests of our shareholders will be diluted. If the price at which we issue capital stock or instruments convertible into capital stock is below the net tangible book value of our stock at such time, there also will be dilution in the net tangible book value of your shares at that time.

Our securities are illiquid and are subject to limitations on transfer.

Our securities should be considered a long-term, illiquid investment. Our securities have not been registered under the Securities Act and cannot be sold without registration under the Securities Act unless an exemption from registration is available. In addition, our securities are not registered under any state securities laws that would permit transfers in individual states. Because of these restrictions and the absence of an active trading market for our securities, it is likely that a stockholder will be unable to liquidate their investment in our securities even though individual financial circumstances would dictate such liquidation.

We have not retained independent professionals for investors.

We have not retained any independent professionals to comment on or otherwise protect the interests of potential investors. Although we have retained our own counsel, neither such counsel nor any other independent professionals have made any examination of any factual matters herein, and potential investors should not rely on our counsel regarding any matters herein described.

You will need to keep records of your investment for tax purposes.

As with all investments in securities, if you sell our securities, you may realize a gain or loss on your investment which is likely to affect your tax position. If you do not have a regular brokerage account, or your regular broker will not hold the securities for you (many brokers refuse to hold certain private securities for their customers), you will have to make other

arrangements for recordkeeping, including possibly keeping your own records for use in calculating any tax effects on any sales of the securities you sell.

RISKS RELATED TO CONTROL BY CERTAIN SHAREHOLDERS/ACQUISITION

Our principal stockholders and management are able to exert significant control over matters subject to stockholder approval and our operations.

As of December 31, 2018, our executive officers, directors, holders of five percent or more of our capital stock and their affiliates beneficially owned approximately 92% of our voting stock. In addition, certain of the above shareholders and their affiliated entities may purchase securities in this offering. Therefore, even after this offering, these shareholders will have the ability to influence us through their ownership position. These shareholders may be able to determine all matters requiring stockholder approval. For example, these shareholders, if they act together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our capital stock that you may believe are in your best interest as one of our security holders.

Provisions of our charter documents, including our Bylaws, our compensatory arrangements, and provisions of Delaware corporation law could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our shareholders, or to remove our current management.

Some provisions of our charter documents and Delaware General Corporation Law could have, if implemented or invoked, anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders, and may prevent attempts by our shareholders to replace or remove current or future management. These provisions include authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which, once authorized, may be issued without further shareholder approval; and

These provisions may frustrate or prevent attempts by our shareholders to replace or remove current or future management by making it more difficult for shareholders to replace members of our board of directors, which is responsible for appointing the members of our management.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested shareholder for a period of three years following the date on which the shareholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our shareholders. Further, other provisions of Delaware General Corporation Law may also discourage, delay or prevent someone from acquiring us or merging with us.

RISKS RELATED TO FINANCIAL REPORTING

We may become subject to securities reporting requirements.

If we become subject to the reporting requirements of the U.S. Securities and Exchange Commission or other securities regulators, we would incur significant additional compliance and administrative costs.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, holders of our securities could lose confidence in our financial and other reporting, which would harm our business and the value of our securities.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement effective or required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to be able to report our financial results appropriately. In addition, any testing of our controls that we may conduct, or testing by an independent registered public accounting firm, may (i) reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or (ii) identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a material and adverse effect on the value of our securities.

Our financial results may vary significantly from year-to-year or quarter-to-quarter due to a number of factors which may lead to volatility in the price of our securities if our securities trade publicly.

Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors that may contribute to these fluctuations include the following, among others:

- our ability to obtain additional funding to develop our product-candidates and the cost of that additional funding; the expenses for clinical trials of our product-candidates;
- delays in the commencement, enrollment and completion of clinical trials, as well as in the analysis and reporting of results from such clinical trials;
- delays in regulatory review and approvals, if any, of product-candidates;
- the expenses involved in seeking regulatory approval of our product-candidates;
- our receipt of regulatory approval to commercialize our products;
- our ability to establish an effective sales and marketing capability;
- competition from existing or new products that may be introduced;
- potential side effects of our product-candidates that could delay or prevent commercialization;
- potential adverse events and resulting product liability claims;
- potential liabilities associated with hazardous materials;
- our ability to obtain and maintain adequate insurance policies;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- the nature of any collaborations we may enter into for our product-candidates;

- our ability, our partners' abilities, and third parties' abilities to protect and assert intellectual property rights;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to attract and retain key personnel to manage our business effectively;
- costs related to involvement in and outcomes of potential litigation;
- fluctuations in foreign exchange rates; and
- our ability to adequately support future growth.

Due to the factors mentioned above and others, the results of any prior quarterly or annual period should not be relied upon as indicative of our results of operations for any future period.

Among other factors, our financial results may be subject to fluctuations in exchange rates between the United States dollar and foreign currencies.

To the extent we conduct business or have operations outside the U.S., we will be subject to risks that typically arise from conducting business internationally, including, among other factors, the risk of foreign exchange volatility. Sales of approved products are likely to be invoiced to customers in the currency used in the customer's country. In addition, we may make purchases and incur certain operating expenses in foreign currencies. We will be exposed to foreign exchange rate volatility as a direct result of our international activities and operations. Foreign exchange rate fluctuations are expected to be recorded on our consolidated results of operations as a component of other income, net. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially affect our results of operations. In addition, in a period where the U.S. dollar is strengthening or weakening relative to a particular foreign currency, our revenues and expenses denominated in such foreign currency will be translated into U.S. dollars at a lower or higher value than they would be had currency exchange rates been unchanged. We may not conduct hedging to mitigate the effects of foreign currency volatility. As a result, our future results of operations could be materially affected by changes in these or other factors.

RISKS RELATED TO DIVIDENDS AND CARRYFORWARDS

We do not intend to pay cash dividends for at least the foreseeable future.

We have never declared or paid any cash dividend on our capital stock. We currently do not anticipate declaring or paying any cash dividends for the foreseeable future. We anticipate that we will retain any future earnings for the development, operation and expansion of our business. Any financial return to stockholders will, therefore, be limited to possible stock appreciation and no appreciation is assured.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," that corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset post-change income may be limited. An "ownership change" is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period. We believe that, with various transactions that have occurred or will occur over various three-year periods,

we may have triggered or may trigger an "ownership change" limitation. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may be limited.

RISKS RELATED TO OUR FACILITIES

The majority of our research and development activities and all of our general and administrative activities are performed in or managed from a variety of facilities.

We are headquartered in the Boston, Massachusetts, area. We operate from a combination of limited office facilities and home offices and use laboratories available to our science co-founders. If we encounter any disruptions to our operations for any reason, we may be prevented from effectively operating our business.

Any losses or damages we incur could have a material adverse effect on our business operation and to the extent we have insurance, it may not cover the cause of such disruption or provide adequate compensation if it does. Our operations may be subject to lengthy business interruption if we are unable to work for any reason and for any length of time.

In addition, computerized information may be lost or damaged, precluding us from being able to perform timely and effective recovery in the event of catastrophic failure of our data storage and backup systems. Significant disruptions of information technology or communications systems, breaches of data security, or other major events could materially and adversely affect us.

WHERE YOU CAN OBTAIN MORE INFORMATION

This PPM contains limited information about the company. While we believe the information contained in the PPM is accurate, such documents are not exhaustive. We cannot guarantee prospective investors that the abbreviated nature of the PPM will not omit information which a prospective investor may believe is important in determining if an investment in our securities is appropriate. As a result, prospective investors are required to undertake their own due diligence of us, our current and proposed business and operations, our management, and our financial condition to verify the accuracy and completeness of the information in this PPM. Prospective investors may make an independent examination of our books, records and other documents to the extent an investor deems it necessary or appropriate and should not rely on us or any of our employees or agents with respect to judgments relating to an investment in the company.

Each prospective investor will be given an opportunity to ask questions of, and receive answers from, our management concerning the terms and conditions of this offering and to obtain any additional information, to the extent the company possesses such information or can acquire it without unreasonable efforts or expense, as necessary to verify the accuracy of the information contained in this PPM.

Any such inquiries or requests for additional information or documents should be made in writing, addressed to us at:

TransCode Therapeutics, Inc.

6 Liberty Square #2382 Boston MA 02109 Attention: Chief Executive Officer Email: <u>michael.dudley@transcodetherapeutics.com</u>

INDEX TO EXHIBITS

Exhibit A – Glossary of Terms

Exhibit B - Form of Subscription Agreement

Exhibit C - Certificate of Incorporation and Bylaws

Exhibit D – Audited Financial Statements

EXHIBIT A – GLOSSARY OF TERMS

| <u>Term</u> | Definition |
|-------------------------|--|
| 5-fluorouracil | Fluorouracil (5-FU), sold under the brand name Adrucil among others, is a medication used to treat cancer. |
| adaptive trial design | An adaptive design is defined as a design that allows modifications to the trial and/or statistical procedures of the trial after its initiation without undermining its validity and integrity. The purpose is to make clinical trials more flexible, efficient and fast. |
| AE | Adverse event reporting |
| antigenicity | The capacity of a substance to induce the formation of antibodies or to elicit an immune response when injected into an animal. |
| antisense | Molecular biologists call a single strand of DNA sense (or positive (+)) if an RNA version of the same sequence is translated or translatable into protein. Its complementary strand is called antisense (or negative (-) sense). |
| arm of a clinical study | An arm of a clinical trial is a group of patients receiving a specific treatment (or no treatment). Trials involving several arms, or randomized trials, treat randomly-selected groups of patients with different therapies in order to compare their medical outcomes. |
| Biomarker | A physiological event or molecule that can be measured. Examples include the presence or absence of a protein or a mutated gene. Biomarkers are often used to indicate the presence or progression of a disease. |
| boxed warnings | Boxed warnings (also known as black box warnings) are special warnings that have been issued by the Food and Drug Administration (FDA) to alert a doctor to a potentially serious side effect of a medicine or to restrictions on the use of the medicine. |
| breakthrough status | Breakthrough therapy is a United States Food and Drug Administration designation that expedites drug development that was created by Congress under Section 902 of the 9 July 2012 Food and Drug Administration |

| | Safety and Innovation Act. The FDA's "breakthrough therapy" designation is not intended to imply that a drug is actually a "breakthrough" or that there is high-quality evidence of treatment efficacy for a particular condition; rather, it allows the FDA to grant priority review to drug candidates if preliminary clinical trials indicate that the therapy may offer substantial treatment advantages over existing options for patients with serious or life-threatening diseases. |
|---------------------------|---|
| broker-dealer | A broker-dealer is a person or firm in the business of buying and selling securities for its own account or on behalf of its customers. |
| Capital stock | Capital stock is the number of common and preferred shares that a company is authorized to issue, according to its corporate charter. |
| cGMP | CGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA. CGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. |
| clinical proof of concept | Proof of Concept studies are mainly conducted in targeted patient populations and are designed to demonstrate early signals of a product's efficacy. |
| Clinical trial | The process of bringing a drug to market. Phase I trials are initial studies to determine the metabolism and pharmacologic actions of drugs in humans, side effects associated with increasing doses, and to gain early evidence of effectiveness. In Phase II, controlled clinical studies evaluate drug effectiveness for patients with the disease and determine the common short-term side effects and risks. Phase III trials are expanded investigations to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling. |
| СМС | To appropriately manufacture a pharmaceutical or biologic specific manufacturing processes, product characteristics, and product testing must be defined in order to ensure that the product is safe, effective and consistent between batches. These activities are known as CMC, chemistry, manufacturing and control. |

| CNS metastasis | Cancer that has spread from the original (primary) tumor to the central nervous system (CNS). Also called central nervous system metastasis. |
|------------------------------|---|
| convertible promissory notes | A convertible promissory note is a debt instrument that converts to equity in the company that issues it when certain conditions outlined in the promissory note are met. The conversion from debt to equity may be voluntary or mandatory depending upon the agreement between the issuer of the note and the investor. |
| CRO | A contract research organization (CRO) is a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. A CRO may provide such services as biopharmaceutical development, biologic assay development, commercialization, preclinical research, clinical research, clinical trials management, and pharmacovigilance. CROs are designed to reduce costs for companies developing new medicines and drugs in niche markets. |
| Crystal City Guideline | Quantitative Bioanalytical Method Validation and Implementation: The 2013 Revised FDA Guidance |
| cynomolgus monkey | The cynomolgus monkey (Macaca fascicularis) is a well- known non-human primate species commonly used in non- clinical research. |
| cytochrome P450 | The cytochrome P450 (P450) family of enzymes is by far the most important component of metabolic drug elimination |
| cytostatic | Cytotoxic drugs or cytostatics (also cytotoxic chemotherapy) are drugs used to destroy cancer cells. Cytotoxic drugs inhibit cell division and in this way cause cancer cells to die. Cytotoxic drugs are transported in the bloodstream throughout the body. |
| Disease Free Survival | In cancer, the length of time after primary treatment for a cancer ends that the patient survives without any signs or symptoms of that cancer. In a clinical trial, measuring the disease-free survival is one way to see how well a new treatment works. Also called DFS, relapse-free survival, and RFS. |

| distant metastases | Refers to cancer that has spread from the original (primary) tumor to distant organs. Also known as distant cancer. |
|----------------------|---|
| doxorubicin | Doxorubicin, sold under the trade names Adriamycin among others, is a chemotherapy medication used to treat cancer. This includes breast cancer, bladder cancer, Kaposi's sarcoma, lymphoma, and acute lymphocytic leukemia. |
| ER | Estrogen receptor |
| FDA | Food and Drug Administration |
| HER2 | HER2 (human epidermal growth factor receptor 2) is a gene that can play a role in the development of breast cancer. |
| hormone receptor | Breast cancer cells often have receptors (proteins) that hormones or other proteins can attach to and stimulate the cancer to grow. A pathologist does tests on the cancer to find out if receptors are present and what type they are. The results help you and your doctor to decide on the most effective treatment for you. |
| Immunogenicity | The ability of a substance to produce an immune response. |
| in vitro | Performed using laboratory apparatus rather than a living animal. |
| in vivo | Involving living animals or humans as test subjects. |
| IND | An Investigational New Drug Application (IND) is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans. |
| IND enabling studies | Regulatory bodies, who grant permission to conduct studies with Investigational New Drugs (INDs), require that a battery of toxicity studies be conducted in animals to understand the potential of the drugs to induce unwanted effects or toxicities. Studies to understand the toxicity potential of test drugs are generally conducted in two species: rodent and non-rodent. The most commonly used rodent species is the rat, though the mouse may also be used provided a strong enough justification supports it use. The non-rodent species of choice are the dog, monkey and |

| | pig. The choice of species largely depends on the class of test drug under investigation and how closely the metabolism of a species mimics that in humans based on in vitro studies. It doesn't always follow that the metabolism in a non-rodent species will mimic that in humans as the species is closer to humans in the evolutionary tree. |
|---------------------------------|--|
| IRB | The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. |
| Lin28b | The RNA-binding proteins LIN28A and LIN28B have diverse functions in embryonic stem cells, cellular reprogramming, growth, and oncogenesis. |
| local metastases | Cancer cells can spread locally by moving into nearby normal tissue. Cancer can also spread regionally, to nearby lymph nodes, tissues, or organs. And it can spread to distant parts of the body. The process by which cancer cells spread to other parts of the body is called metastasis. |
| locked nucleic acid oligo (LNA) | In locked nucleic acids (LNAs), the ribose ring is locked in a particular conformation by the introduction of a 2'-O-,4'- C methylene bridge, which increases the affinity for complementary RNA or DNA. LNAs are used to increase the sensitivity and specificity of molecular biology tools such as DNA microarrays and LNA-based oligonucleotides are being developed as antisense therapies. |
| metastases | Metastases (the plural form of metastasis) most commonly develop when cancer cells break away from the main tumor and enter the bloodstream or lymphatic system. |
| metastasis | Metastasis is the medical term for cancer that spreads to a different part of the body from where it started. When this happens, doctors say the cancer has "metastasized." Other names for metastasis are "metastatic cancer" and "stage 4 cancer." |
| metastatic burden | Metastatic burden is the amount of metastatic tumor tissue. |
| metastatic cell | A cancer cell that breaks away from the main tumor |

| metastatic lesion | Metastatic lesion is a tumor at a secondary (metastatic) organ. An example is tumor in the liver, brain, bone, or lungs for a cancer that originated in the breast or prostate. |
|---------------------|---|
| microRNA | A short segment of RNA that suppresses gene expression by binding to complementary segments of messenger RNA and interfering with the formation of proteins by translation |
| MRI | Magnetic resonance imaging (MRI) is a medical imaging technique used in radiology to form pictures of the anatomy and the physiological processes of the body in both health and disease. MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body. |
| murine cancer model | Mouse cancer model |
| nanomolar | Molar concentration (also called molarity, amount concentration or substance concentration) is a measure of the concentration of a chemical species, in particular of a solute in a solution, in terms of amount of substance per unit volume of solution. Describing concentrations one billionth (10-9) of molar. |
| nanoparticle | A nanoparticle (or nanopowder or nanocluster or nanocrystal) is a microscopic particle with at least one dimension less than 100 nm. |
| nanosensor | Nanosensors convey information about nanoscale materials to the macroscopic world – that is, to a human observer or electrical device. These sensors can be manufactured to detect differences in volume, speed, gravity, electrical charge, chemical composition, pressure, temperature or any number of other physical changes. They may soon be used to detect chemicals such as disease biomarkers, or create nanocircuits with changeable conductivity. |
| NDA | New Drug Application |
| NIH | National Institutes of Health |
| non-coding RNA | A non-coding RNA (ncRNA) is a functional RNA molecule that is transcribed from DNA but not translated into proteins. |

| non-GLP | Non-GLP (Good Laboratory Practices) studies do not require all of the rigor of GLP studies. Although GLP is written into the Official Register of the United States, compliance with GLP is not required for in vitro drug metabolism and drug interaction studies. Compliance to GLP requirements is not required for discovery, basic research, screening or other studies where the safety of a product is not being assessed. |
|-----------------|---|
| oligonucleotide | The term "oligonucleotide" or "oligo" usually refers to a synthetic laboratory-made DNA or RNA strand. |
| overexpression | Excessive expression of a gene (as that caused by increasing the frequency of transcription. |
| PCR | Polymerase chain reaction (PCR) is a method widely used in molecular biology to make multiple copies of a specific DNA segment. PCR is now a common and often indispensable technique used in medical laboratory and clinical laboratory research for a broad variety of applications including biomedical research |
| PD marker | Pharmacodynamic (PD) markers monitor biological effects used in decision making in early drug development. PD markers are used in pre-clinical and clinical studies for establishing doses and dosing regimen for future studies. |
| PD-L1 | PD-1 and PD-L1 are types of proteins found on cells in your body. PD-L1 protein is found on immune cells called T cells. It normally acts as a type of "off switch" that helps keep the T cells from attacking other cells in the body. PD- 1 attaches to PD-L1, a protein found on some normal (and cancer) cells. This interaction basically tells the T cell to leave the other cell alone and not attack it. Some cancer cells have large amounts of PD-L1, which helps them hide from immune attack. |
| pharmacokinetic | Pharmacokinetics is currently defined as the study of the time course of drug absorption, distribution, metabolism, and excretion. Clinical pharmacokinetics is the application of pharmacokinetic principles to the safe and effective therapeutic management of drugs in an individual patient. |
| Pharmacology | Pharmacology is the study of how substances interact with living organisms to produce a change in function. |

| Phases of clinical trial | Human Clinical Trial Phases. Phase I studies assess the safety of a drug or device. Phase II studies test the efficacy of a drug or device. Phase III studies involve randomized and blind testing in several hundred to several thousand patients. |
|---------------------------|--|
| PhIIa | Phase IIa clinical trial |
| PR | Progesterone receptor |
| pre-clinical | In drug development, preclinical development, also named preclinical studies and nonclinical studies, is a stage of research that begins before clinical trials (testing in humans) can begin, and during which important feasibility, iterative testing and drug safety data are collected. |
| Progression Free Survival | The length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse. In a clinical trial, measuring the progression-free survival is one way to see how well a new treatment works. |
| R&D | Research and Development |
| regression | A decrease in the size of a tumor or in the extent of cancer in the body. |
| SBIR | The Small Business Innovation Research (or SBIR) program is a United States Government program, coordinated by the Small Business Administration, intended to help certain small businesses conduct research and development (R&D). Funding takes the form of contracts or grants. The recipient projects must have the potential for commercialization and must meet specific U.S. government R&D needs. |
| tamoxifen | Tamoxifen is the oldest and most-prescribed selective estrogen receptor modulator (SERM). Tamoxifen is approved by the U.S. Food and Drug Administration (FDA) to treat women and men diagnosed with hormone-receptor- positive, early-stage breast cancer after surgery (or possibly chemotherapy and radiation) to reduce the risk of the cancer coming back (recurring) and for women and men diagnosed with advanced-stage or metastatic hormone- receptor-positive disease. |

| therapeutic efficacy | The word efficacy is used in pharmacology and medicine to refer both to the maximum response achievable from a pharmaceutical drug in research settings, and to the capacity for sufficient therapeutic effect or beneficial change in clinical settings. |
|----------------------|--|
| ТК | Toxicokinetics is the study of systemic exposure during toxicological experiments. |
| toxicity | Toxicity is the degree to which a chemical substance or a particular mixture of substances can damage an organism. |
| Transfer agent | A transfer agent is a trust company, bank or similar financial institution assigned by a corporation to maintain records of investors and account balances. |
| transporters | Membrane transporters can have clinically relevant effects on the pharmacokinetics and pharmacodynamics of a drug in various organs and tissues by controlling its absorption, distribution, and elimination. Transporters are expressed in tissues throughout the human body and govern the access of endogenous and exogenous substances to various sites in the body. |
| Treasury stock | Treasury stock is a corporation's previously issued shares of stock which have been repurchased from the stockholders and the corporation has not retired the repurchased shares. |
| Triple-negative | A diagnosis of triple negative breast cancer means that the three most common types of receptors known to fuel most breast cancer growth–estrogen, progesterone, and the HER-2/neu gene– are not present in the cancer tumor. |
| TTX-MC138 | TransCode's initial therapeutic to treat metastatic cancer. |
| visceral crisis | Visceral crisis is defined as severe organ dysfunction as assessed by signs and symptoms, laboratory studies, and rapid progression of disease. |
| warrant | In finance, a warrant is a security that entitles the holder to buy the underlying stock of the issuing company at a fixed price called exercise price until the expiry date. Warrants and options are similar in that the two contractual financial instruments allow the holder special rights to buy securities. |

EXHIBIT B – FORM OF SUBSCRIPTION AGREEMENT

Available on Manhattan Street Capital website:

https://www.manhattanstreetcapital.com/TransCode-Therapeutics

EXHIBIT C – FORM OF CERTIFICATE OF INCORPORATION AND BYLAWS

EXHIBIT D – AUDITED FINANCIAL STATEMENTS