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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from _____ to _____

Commission File Number 001-37411

TIMBER PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**59-3843182**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

110 Allen Road, Suite 401 Basking Ridge, NJ 07920
(Address of principal executive offices and zip code)

(973) 314-9577
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	TMBR	The NYSE American, LLC

Indicate by check mark whether the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Act. YES ☐ NO ☒

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

Indicate by check mark whether the registrant has submitted electronically, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller Reporting Company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal controls over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of June 30, 2021, the last day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of the shares of the Registrant's common stock held by non-affiliates was $44.6 million, based upon the closing price of the Registrant's common stock as reported on the NYSE American on June 30, 2021 of $1.22 Shares of the Registrant's common stock held by each executive officer and director and by each person who owns 10 percent or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 15, 2022, there were outstanding 63,696,836 shares of the registrant's common stock, $0.001 par value.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement relating to the 2022 Annual Meeting of Stockholders, scheduled to be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2021, are incorporated by reference into Part III of this Annual Report on Form 10-K.

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
Form 10-K

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The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report, particularly those under "Risk Factors." Additionally, many of these risks and uncertainties are currently elevated by and may or will continue to be elevated by the novel coronavirus ("COVID-19") pandemic. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our lack of operating history and history of operating losses;
- our current and future capital requirements and our ability to satisfy our capital needs, including our ability to access financing that may be unavailable due to contractual limitations under the Securities Purchase Agreement (as defined below);
- the dilutive effect of our outstanding convertible securities:
- our ability to successfully complete required clinical trials of our products and obtain approval from the U.S. Food and Drug Administration ("FDA") or other regulatory agents in different jurisdictions;
- the potential impact of outbreaks of communicable diseases, including the COVID-19 pandemic, and adverse global conditions, including political and economic uncertainty on our business, financial conditions, and results of operations, including on our clinical development plans and timelines;
- the outcome, costs and timing of clinical trial results for our current or future product candidates;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- the volatility of the price of our common stock;
- our ability to retain key executives;
- our ability to internally develop new inventions and intellectual property;
- acceptance of our products in our industry;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

ADDITIONAL NOTES

- Timber Pharmaceuticals, Inc. and its consolidated subsidiaries are referred to herein as "Timber," "the Company," "we," "us," and "our," unless the context indicates otherwise.

- Amounts and percentages throughout this Annual Report on Form 10-K may reflect rounding adjustments and consequently totals may not appear to sum.

PART I

ITEM 1. BUSINESS

Overview

Timber Pharmaceuticals, Inc. ("Timber", the "Company", "we", "us") is a clinical-stage biopharmaceutical company focused on the development and commercialization of treatments for orphan dermatologic diseases. Our investigational therapies have proven mechanisms-of-action backed by decades of clinical experience and well-established CMC (chemistry, manufacturing and control) and safety profiles. We are initially focused on developing non-systemic treatments for rare dermatologic diseases including congenital ichthyosis ("CI"), facial angiofibromas ("FAs") in tuberous sclerosis complex ("TSC"), and sclerotic skin diseases. Our lead mid to late-stage programs are TMB-001 and TMB-002. TMB-003 is our earliest stage program.

TMB-001

TMB-001, a patented topical formulation of isotretinoin using our patented IPEG™ delivery system, completed its Phase 2b clinical trial (the CONTROL study) in Q4 of 2021, for the treatment of moderate to severe subtypes of CI, a group of rare genetic keratinization disorders that lead to dry, thickened, and scaling skin. This study demonstrated a clinically meaningful reduction in targeted and overall severity of CI along with a favorable safety profile. A prior Phase 1/2 study involving 19 patients with CI demonstrated safety and a signal of preliminary efficacy of TMB-001, as well as minimal systemic absorption. The U.S. Food and Drug Administration ("FDA") (through its Orphan Products Grant program) awarded us a $1.5 million grant to support clinical trials evaluating TMB-001.

There are currently no FDA approved treatments for CI, however, oral isotretinoin is commonly used off label. Isotretinoin was first approved in the United States by the FDA as ACCUTANE® and was formulated as an oral product to treat severe recalcitrant nodular acne. No topical forms of isotretinoin have ever been approved in the US. Although oral isotretinoin is used off label for patients with CI, common and potentially serious systemic side effects limit its utility as a chronic treatment. We believe a topical isotretinoin could potentially provide benefit to patients with CI without the systemic side effects. The systemic side effects of oral isotretinoin can include teratogenicity, pancreatitis, elevations of serum triglycerides, psychiatric disorders, and skeletal hyperostosis, among others.

In a proof-of-concept Phase 1/2- clinical trial, TMB-001 was found to be well tolerated and demonstrated evidence of an efficacy signal supported by improvement in the Investigator's Global Assessment ("IGA") scale and CI signs/symptoms at the end of Parts 1 and 2 of the Phase 1/2 trial. A favorable efficacy signal was further supported in Part 2 of the study where an overall IGA improvement was observable in about half the subjects initially treated with vehicle after receiving 4 weeks of treatment with TMB-001.

On October 7, 2021, we announced the completion of our Phase 2b trial in CI. The Phase 2b CONTROL study was a randomized, double-blind, vehicle-controlled study designed to assess the efficacy and safety of two concentrations of TMB-001 (0.05% and 0.1% isotretinoin) for the treatment of two distinct subtypes of moderate-to-severe CI (X-linked recessive and lamellar ichthyosis) in patients (n=33) nine years old or older. Subjects applied TMB-001 twice daily for 12 weeks. The primary endpoint was the reduction of targeted ichthyosis severity, determined by a 50 percent or greater reduction in the validated Visual Index for Ichthyosis Severity ("VIIS") scaling score (or VIIS-50), a clinically meaningful change. Secondary endpoints included reduction in overall ichthyosis severity, as measured by a two-point improvement

using the (IGA) scale, also considered to be a clinically relevant improvement. The study was not designed or powered for statistical analysis of the endpoints and was intended to provide information for future development.

Top-line results including descriptive statistics are described below:

- In the per protocol (the "PP") population, 100 percent (nominal p= .04) and 40 percent (nominal p= ns) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved VIIS-50 compared to 40 percent in the vehicle group.

- In the intent to treat (the "ITT") population, 64 percent (nominal p= 0.17) and 40 percent (nominal p= ns) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved VIIS-50 compared to 33 percent in the vehicle group.

- In the PP population, 100 percent (nominal p=.002) and 60 percent (nominal p=ns) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved a ≥2 point improvement in the IGA at week 12 compared to 10 percent in the vehicle group.

- In the ITT population, 55 percent (nominal p=.02) and 40 percent (nominal p=ns) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved a ≥2 point improvement in the IGA at week 12 compared to 8 percent in the vehicle group.

- TMB-001 was generally well tolerated with a similar incidence of adverse events (AEs) across treatment groups. The most frequent AEs were local adverse effects common for such topical treatments. There were no treatment-related serious adverse events (SAE).

On February 3, 2022, we announced the successful completion of an End-of-Phase 2 meeting with the FDA that resulted in a clear path to progress to a pivotal Phase 3 study for TMB-001. The clinical development program for TMB-001 includes a Phase 3 study with an efficacy arm and a maximum use pharmacokinetic arm as well as a smaller bridging study required to bridge to the oral reference product. Based on FDA feedback at the End-of-Phase 2 meeting, we intend to initiate a pivotal Phase 3 study of TMB-001 in mid-2022.

On March 25, 2022, we announced a late-breaking presentation of a sub-analysis of the Company's Phase 2b CONTROL study that evaluated TMB-001 was made by a third party at the American Academy of Dermatology 2022 Annual Meeting. The sub-type analysis found that TMB-001 0.05% demonstrated a substantially greater proportion of patients achieving VIIS-50 and ≥2-grade IGA improvement compared with vehicle regardless of subtype. Among enrolled patients (TMB-001 0.05% [n=11], 0.1% [n=10], and vehicle [n=12]), 55% had ARCI-LI and 45% XLRI subtypes.

On December 15, 2020, we announced that we had received a notice of allowance from the U.S. Patent and Trademark Office (USPTO) for a patent application covering TMB-001, (U.S. Patent Application No.: 15/772,456) and the application subsequently issued on March 2, 2021, as US 10,933,018.

On July 14, 2021, September 9, 2021, and September 17, 2021, we were granted patents for TMB-001 in Japan (No. 6901670), Australia (No. 2016346203), and China (No. ZL201680063866.4), respectively. Additional patents are pending for TMB-001 in several other countries.

TMB-002

TMB-002, a proprietary topical formulation of rapamycin, is currently being evaluated in a Phase 2b clinical trial for the treatment of facial angiofibromas ("FAs") in Tuberous Sclerosis Complex ("TSC"), a multisystem genetic disorder resulting in the growth of hamartomas in multiple organs. TSC results from dysregulation in the mTOR pathway, and as a topical mTOR inhibitor, TMB-002, marketed under the brand name Pascomer®, may address FAs in TSC without the level of systemic absorption of an oral agent. According to the Tuberous Sclerosis Alliance, one in 6,000 babies are born with TSC and nearly one million people are estimated to have TSC globally (approximately 50,000 in the U.S.). Common

symptoms of TSC include skin lesions, cerebral pathology, seizures, renal pathology and retinal hamartomas. We believe there is a need for a simple, non-invasive treatment option of FAs. Pharmacologic treatment options include oral rapamycin (also known as sirolimus) for the treatment of renal and neurological manifestations of TSC and has been a treatment option for FAs as well, although the systemic side effects of oral rapamycin have limited its utility in the treatment of FAs.

Preclinical studies of TMB-002 have demonstrated a positive toxicity profile. We initiated a Phase 2b dose response study, evaluating the dose-dependent efficacy of TMB-002 in the treatment of FAs associated with TSC compared with vehicle.

As of April 30, 2021, all sites participating in a Phase 2b clinical trial evaluating TMB-002 were opened and are currently enrolling patients. Site activation and patient enrollment and data collection were impacted by the COVID-19 pandemic in the larger and longer TMB-002 study. Currently, we can confirm that recruitment has been finalized on the TMB-002 Phase 2b trial with a total of 114 consented (108 randomized) patients. We expect to receive top line results from this trial in the third quarter of 2022.

On March 17, 2021, we announced that AFT Pharmaceuticals Limited (“AFT”), our development partner for TMB-002, entered into a license and supply agreement with Desitin Arzneimittel GmbH (“Desitin”) for Pascomer® for the treatment of FAs associated with TSC in Europe. Pursuant to our licensing and development agreement, we are entitled to receive 50% of the economics (royalties and milestones) in any licensing transaction that AFT executes outside of North America, Australia, New Zealand, and Southeast Asia. The current transaction with Desitin is included in the scope of this provision and as such in the third quarter of 2021 we received €250,000 related to an upfront milestone payment paid to AFT by Desitin during the quarter ended September 30, 2021, and recorded revenue of approximately $0.3 million in our financial statements.

TMB-003

The earliest stage product in our pipeline is TMB-003, a proprietary formulation of Sitaxsentan, a new chemical entity in the U.S., which is a selective endothelin-A receptor antagonist. It is currently in preclinical development as a locally applied formulation for the treatment of sclerotic skin diseases. The two disease areas under consideration include Lichen Sclerosis and Localized Scleroderma.

Lichen Sclerosis is a rare chronic disease of vulvae and perianal areas which affects approximately 160,000 women in the US (based on Timber estimates). Lichen Sclerosis affects both sexes but is predominant in women. It has a prevalence 0.1-1.7% of women and is diagnosed to a greater degree by gynecologists rather than dermatologists. Typically, there is a bimodal presentation of pre-pubertal girls and post-menopausal women. The condition is also associated with other autoimmune diseases in 28% of women (e.g., morphea, autoimmune thyroiditis, alopecia areata, vitiligo, pernicious anemia).

Lichen Sclerosis can significantly affect a patient’s quality of life. The condition can be disfiguring and extremely pruritic. It may also be a precursor to squamous cell carcinoma of the vulva and extremely painful.

There are currently no FDA approved treatments for any cutaneous symptoms of Lichen Sclerosis. Ultrapotent corticosteroid ointments (e.g., clobetasol) are used as primary therapy. Using ultrapotent steroids has shown a 96% improvement in symptoms but only 23% of patients return to normal skin, and 68% experience a partial return to normal skin highlighting an unmet need in this condition.

Scleroderma is a chronic connective tissue disease that is generally classified as one of the autoimmune rheumatic diseases. There are two major classifications of scleroderma: Localized Scleroderma and Systemic Sclerosis. While both types of scleroderma will have cutaneous symptoms, Systemic Sclerosis will also affect other organ systems. Localized Scleroderma manifests as an excess production of collagen resulting in a thickening of the skin and connective tissue affecting approximately 90,000 people in the U.S. and an estimated two million globally, according to the Scleroderma Foundation.

One of the most commonly visible symptoms of the disease is hardening of the skin and symptoms can vary from patient-to-patient, ranging from very mild to very severe and can affect mobility, impair growth of limbs, and cause severe

disfigurement. The severity will depend on which part, or parts, of the body is affected and to what extent. If not treated timely and properly, a mild case can become more serious. Localized Scleroderma is more common in children and can be considered a pediatric condition. Currently, there are no approved treatments for the cutaneous symptoms of either type of scleroderma.

Sitaxsentan is a highly selective ET-A receptor antagonist that was originally developed as an oral tablet for treating Pulmonary Arterial Hypertension ("PAH"). Sitaxsentan gained regulatory approval in Europe, Canada, and Australia but was voluntarily withdrawn from the market within five years based on emerging safety concerns, particularly those associated with liver toxicity. Consequently, Sitaxsentan never gained FDA approval in the U.S. We expect such safety concerns can be greatly mitigated through our approach and formulation efforts of pursuing TMB-003 as a localized treatment.

In a series of preclinical studies, Sitaxsentan was shown to significantly reduce fibroblast migration, induce apoptosis, and reduce the amount of collagen produced in TGF-b1 induced human dermal fibroblasts. Further, Sitaxsentan was shown to be significantly better than Bosentan, a non-selective endothelin receptor antagonist, in all of the above measures. These results suggest that TMB-003 may have the potential to effectively treat scleroderma.

On January 12, 2021, we announced that the FDA has granted orphan drug designation for TMB-003, our locally delivered formulation of Sitaxsentan, for the treatment of Systemic Sclerosis. We are planning to pursue additional orphan drug designations in other indications.

BPX-01 and BPX-04

In connection with the merger with BioPharmX Corporation on May 18, 2020, we acquired the BPX-01 and BPX-04 assets. BPX-01 is a Phase 3 ready topical minocycline for the treatment of inflammatory lesions of acne vulgaris. BPX-04 is a Phase 3 ready topical minocycline for the treatment of papulopustular rosacea. We are seeking to monetize these assets through a license, co-development, or sale. On September 15, 2020, we announced that we had received a notice of allowance from the U.S. Patent and Trademark Office (USPTO) for a Company patent application covering BPX-01 and BPX-04 (U.S. Patent Application No.: 16/514,459) and the application subsequently issued on January 5, 2021, as US 10,881,672.

November 2021 Offering

On November 2, 2021, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC, as representative of the several underwriters named in Schedule I thereto, relating to the public offering, issuance and sale of shares of our common stock and, to certain investors, pre-funded warrants to purchase shares of common stock, and accompanying warrants to purchase shares of our common stock. After giving effect to the sale of additional shares pursuant to the exercise of the option by H.C. Wainwright & Co., LLC that closed on November 9, 2021, the total number of shares of common stock (or common stock equivalents) sold by us in the offering was 26,953,125, together with warrants to purchase up to 26,953,125 shares of common stock issued at the closing on November 5, 2021, for total gross proceeds of $17.25 million before deducting underwriting discounts and commissions and other offering expenses, and net proceeds of approximately $15.8 million. As a result of the offering, the exercise price of the Bridge Warrants was adjusted to $0.31 per share.

Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a warrant to purchase one share of common stock. All the securities sold in the offering were sold by the Company. The public offering price of each share of common stock and accompanying common warrant was $0.64 and $0.639 for each pre-funded warrant and accompanying common warrant. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of common stock and were exercised in full on November 5, 2021. The warrants were immediately exercisable at a price of $0.70 per share of common stock and expire five years from the date of issuance.

Asset Purchase Agreements with Patagonia Pharmaceuticals LLC ("Patagonia")

On February 28, 2019, we acquired the intellectual property rights for a topical formulation of isotretinoin for the treatment of CI and identified as TMB-001, formerly PAT-001 including the IPEG™ brand, from Patagonia (the "TMB-001 Acquisition"). Zachary Rome, a member of our board of directors and our former Executive Vice-President and Chief Operating Officer serves as President of Patagonia and also maintains an ownership interest therein.

Under the terms of the TMB-001 Acquisition, we paid a one-time upfront payment of $50,000 to Patagonia. Patagonia is entitled to up to $27.0 million of cash milestone payments relating to certain regulatory and commercial achievements of the TMB-001 Acquisition, with the first being $4.0 million from the initiation of a Phase 3 pivotal trial, as agreed with the FDA. In addition, Patagonia is entitled to net sales earn-out payments ranging from low single digits to mid-double digits for the program licensed. We are responsible for all development activities under the license. As of December 31, 2021,the potential regulatory and commercial milestones were not yet considered probable, and no milestone payments have been accrued at December 31, 2021 or 2020, respectively.

On June 26, 2019, we acquired the intellectual property rights for a locally administered formulation of Sitaxsentan for the treatment of cutaneous fibrosis and/or pigmentation disorders, and identified as TMB-003, formerly PAT-S03, from Patagonia (the "TMB-003 Acquisition").

Upon closing of the TMB-003 Acquisition, we paid a one-time upfront payment of $20,000 to Patagonia. Patagonia is entitled to up to $10.25 million of cash milestone payments subject to adjustments relating to certain regulatory and commercial achievements of TMB-003, with the first being a one-time payment of $250,000 upon the opening of an investigational new drug ("IND") with the FDA. In addition, Patagonia is entitled to net sales earn-out payments ranging from low to mid-single digits for the program licensed. We are responsible for all development activities under the license. The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 or 2020, respectively.

Acquisition of License from AFT Pharmaceuticals Limited ("AFT")

On July 5, 2019, we entered into a license agreement with AFT which provides us with (i) an exclusive license to certain licensed patents, licensed know-how and AFT trademarks to commercialize the Pascomer® product in the United States, Canada and Mexico and (ii) a co-exclusive license to develop the Pascomer® product in this territory. Concurrently, we granted to AFT an exclusive license to commercialize the Pascomer® product outside of its territory and co-exclusive sublicense to develop and manufacture the licensed product for commercialization outside of its territory (the "AFT License Agreement").

The AFT License Agreement also provides for the formation of a joint steering committee to oversee, coordinate and review recommendations and approve decisions with respect to the matters related to the development and commercialization of Pascomer®, in which both the Company and AFT have the right to appoint two members. The committee is currently comprised of three members. We have final decision-making authority on all matters relating to the commercialization of Pascomer® in the specified territory and on all matters related to the development (and regulatory approval) of Pascomer®, with certain exceptions.

The development of Pascomer® is being conducted pursuant to a written development plan, written by AFT and approved by the joint steering committee, which is reviewed on at least an annual basis. AFT shall perform clinical trials of Pascomer® in the specified territory and shall perform all CMC (chemistry, manufacturing and controls) and related activities to support regulatory approval. We are responsible for all expenses incurred by AFT during the term of the AFT License Agreement and shall equally share all costs and expenses with AFT, incurred by AFT for development and marketing work performed in furtherance of regulatory approval and commercialization worldwide, outside of the specified territory. We are also entitled to receive a significant percentage of the economics (royalties and milestones) in any licensing transaction that AFT executes outside of North America, Australia, New Zealand, and Southeast Asia.

Upon closing of the AFT License Agreement, we were obligated to reimburse AFT for previously spent development costs, subject to certain limitations and were obligated to pay a one-time, irrevocable and non-creditable upfront payment

to AFT, payable in scheduled installments. AFT is entitled to up to $25.5 million of cash milestone payments relating to certain regulatory and commercial achievements TMB-002, with the first payment of $1.0 million upon the successful completion of a Phase 2b trial where the results of such clinical trial meet the clinical trial's primary clinical endpoints. In addition, AFT is entitled to net sales royalties ranging from high single digits to low double digits for the program licensed. The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 or 2020, respectively.

Recent Developments

TMB-001 Patents

On March 2, 2021, we were granted a patent (US Patent No. 10,933,018) for TMB-001.

On, February 8, 2022, we submitted a request to register a further pending Chinese divisional patent application (No. 202110920456.X) in Hong Kong.

Officer Resignation

On March 4, 2022, Zachary Rome stepped down from his positions as the Chief Operating Officer and Executive Vice-President of the Company. As a result of his resignation, Mr. Rome (i) was entitled to 79,326 shares of common stock underlying vested VARs, or $22,528, at the Company's election, and (ii) forfeited 52,884 VARs. Mr. Rome continues to serve on the Company's board of directors. On March 4, 2022, Mr. Rome received 59,696 shares of common stock net upon exercise of the VARs after tax withholding.

Background of Topical Isotretinoin (TMB-001)

We are developing a treatment for CI with our product TMB-001, a topical isotretinoin ointment. CI is a large, heterogeneous family of inherited skin disorders of cornification resulting from an abnormality of skin keratinization. The main features of the disorder are scaling and often thickening of the skin.

TMB-001 leverages our patented IPEG™ delivery system. This technology was developed to topically deliver active pharmaceutical ingredients for which a precise cutaneous distribution is essential. The IPEG™ platform utilizes specific ratios of different molecular weight polyethylene glycols to target specific dermal delivery profiles. TMB-001 was designed to maximize delivery of isotretinoin into the pathologic layers of skin while minimizing any systemic absorption.

Completed Phase 2a Multicenter, POC Study

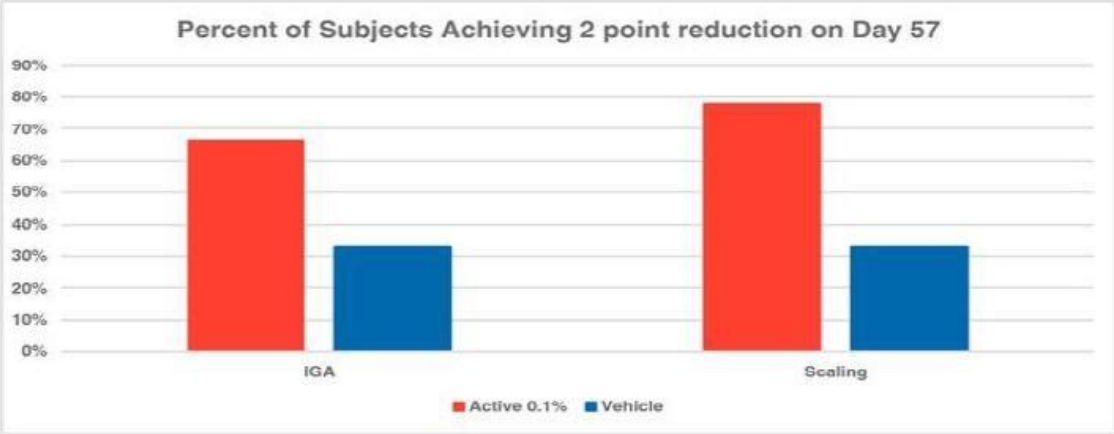
The pilot Phase 2a multicenter, proof-of-concept study of topically applied 0.1% and 0.2% isotretinoin ointment, or TMB-001, in 19 subjects 12 years and older with CI of either the ARCI-LI or XRI subtypes was completed in 2018. Of the 19 subjects enrolled, 10 were randomized at baseline to the TMB-001, 0.1% Treatment Group, and 9 were randomized to TMB-001, 0.2%. In total, 12 subjects (12/19, 63.2%) completed the study and 7 subjects (7/19, 36.8%) discontinued early. Subjects who did not complete the study discontinued due to an adverse event, lost to follow-up, or withdrawal by the subject.

The primary objective of the Phase 2a study was to assess the safety and tolerability of topical TMB-001. Safety was assessed based on the incidence (severity and causality) of any local and systemic adverse events (AEs); number of subjects with presence (and severity) of each individual local skin reaction (LSR): stinging/burning, pain, and pruritus, collected at each time point for each Treatment Area; vital signs at Days 29, 57, and 84; and clinical laboratory tests (hematology, chemistry, and urinalysis) at Days 29, 57, and 84. 28 treatment-emergent adverse events ("TEAEs") were reported in 14 (out of 19) subjects (seven out of ten for TMB-001 0.1% and 7/9 for TMB-001 0.2%). The most common TEAEs were in the General disorders and Administration Site Conditions System Organ Class (four out of ten for TMB-001 0.1% and three out of nine for TMB-001 0.2%), namely application site pruritus, application site irritation, and application site dermatitis. The majority of TEAEs were mild and deemed not related to test article in both groups. Of the 8 subjects with TEAEs that were possibly, probably, or definitely related to treatment (e.g., application site rash, application site irritation,

dermatitis contact, application site dermatitis, application site pruritus, application site folliculitis, application site pain), all had interruptions or withdrawal of the study drug. Overall, the majority of burning/stinging, pain, and pruritus local skin reactions ("LSRs") was mild or moderate for both Treatment Areas in the 0.1% and 0.2% groups with somewhat greater directional severity in the 0.2% group. In Part 1 for both treatment groups, there was a modest increase over time in LSRs in the Treatment Area that received Active compared with the Treatment Area that received vehicle, particularly for pruritus. In Part 2, subjects who continued to apply active test article did not generally have increased LSRs, however, there was a modest increase in the proportion of subjects that received vehicle in Part 1 who reported pruritus at Day 84 in both treatment groups. Reports of severe LSRs were low, but slightly higher in the areas that were treated with Active for 12 weeks. Pruritus was the most commonly reported LSR at Baseline and post-Baseline visits. In the 0.2% group, one subject had a serious adverse event ("SAE"), namely severe mental status change and 2 TEAEs (moderate gastroenteritis norovirus and moderate Clostridium difficile colitis) that led to study discontinuation but recovered/resolved by end of study and the adverse events were all deemed not related to test article. There were no clinically significant changes from Baseline in laboratory test results and vital signs to end of study ("EOS") laboratory test results and vital signs, save for the one subject who discontinued due to an SAE (deemed unrelated to test article; mental status change due to acute encephalopathy, most likely secondary to the side effects of multiple medications with sedative side effects) and had an increase in blood triglycerides that were deemed clinically significant at the end of the study.

The secondary objective of the study was to explore evidence of a potential efficacy signal of the active test article compared to vehicle and to explore the plasma levels of isotretinoin and tretinoin from topically applied TMB-001 with comparison to background systemic retinoid levels pre- and post-treatment. Efficacy endpoints were assessed using the IGA scale where the overall severity was assessed using a 5-point IGA scale where 0 was clear, 1 was almost clear, 2 was mild, 3 was moderate, and 4 was severe and individual clinical signs and symptoms where the overall severity of erythema, scaling, fissuring, and papulation/lichenification was graded using a 5-point scale where 0 was clear, 1 was almost clear, 2 was mild, 3 was moderate, and 4 was severe.

The below graph represents the primary measures of the change in IGA and scaling relative to baseline at Day 57 for the 0.1% concentration.



A favorable efficacy signal was further supported in Part 2 of the study where overall IGA and scaling improvement was observable in about half of the subjects initially treated with vehicle after receiving 4 weeks of treatment with TMB-001 Ointment. For the majority of subjects in both treatment groups, the active arms maintained the same IGA score at Day 84 as was observed at Day 57.

Plasma concentrations of isotretinoin and tretinoin indicated that systemic exposure was minimal within the four hours following initial application. Trough concentrations measured on Days 8, 29, 57 and 84 approximately 12 hours following the preceding dose indicated that systemic concentrations of isotretinoin and tretinoin were within range of the endogenous levels measured at Baseline prior to the first application.

Completed Pre-Clinical Studies

Dermal pharmacokinetic/toxicokinetic ("PK/TK") and dermal toxicity studies for TMB-001 have been completed. The initial preclinical studies were completed with a slightly different formulation, PATP03 AN. However, following these studies, the formulation was modified and formulation PATPO3 ANR was selected for further clinical development. The permeability potential of these 2 formulations of TMB-001 Ointment, 0.2% (PATPO3 AN [prior formulation] and PATPO3 ANR [clinical formulation]) was assessed in an in vitro Franz cell assay using skin from a single volunteer and showed no significant differences in many parameters. To date, all nonclinical studies have been conducted using the PATPO3 AN formulation. The differences between PATPO3 AN and PATP03 ANR are minor and, predominantly, include the removal of ethanol and water and an adjustment of average PEG molecular weight in the clinical formulation. These changes do not represent a safety concern as the safety of high molecular weight PEGs, including those used in the clinical formulation, is well established. A series of nonclinical studies have been conducted using TMB-001 Ointment with concentrations ranging from 0.025% to 0.2% to support later stages of development (e.g., Phase 3 clinical studies) and an eventual New Drug Application. Information on all aspects of the pharmacological activity of isotretinoin is available in published literature. The PK of isotretinoin following systemic administration have been well characterized. Absorption tends to be fairly rapid with high distribution to the liver. Transplacental distribution of isotretinoin has been established in all nonclinical species.

The repeat-dose toxicity and local tolerance of TMB-001 Ointment have been evaluated in minipigs, bovine cornea, guinea pigs, and rabbits using formulation PATPO3 AN. Topical application of the formulated product (ranging from 0.05% to 0.2%) in minipigs for 90 days produced changes at the site of application only including irritation and microscopic alterations. The severity increased with increasing concentration. These types of dermal changes are consistent with those observed in patients administered a topical formulation of isotretinoin. TMB-001 Ointment did not produce serious eye damage, sensitization in guinea pigs, or phototoxicity in rabbits. As noted previously, the formulation used in the toxicity studies (PATPO3 AN) is different than the one selected for clinical development (PATPO3 ANR). The toxicity profile of isotretinoin administered via oral or other systemic routes of dosing is well characterized. Of particular concern from a safety perspective is its teratogenicity. It is important to differentiate the toxicity of isotretinoin observed following systemic (oral) dosing with that noted following topical administration. The pre-clinical data demonstrates that the low exposures to isotretinoin achieved with TMB-001 Ointment correlate with no adverse systemic effects. In comparison, the toxicity reported in the literature following oral administration, including teratogenicity, is associated with markedly higher exposures. Overall, there are no new or unique toxicities observed in animals treated with TMB-001 Ointment, 0.2%. The observations are consistent with the effects of isotretinoin.

Completed Phase 2b "CONTROL" Study

We initiated a Phase 2b randomized, parallel, double-blind, vehicle-controlled study in December 2019. The purpose of this study was to investigate the efficacy and safety of two concentrations of topically applied TMB-001 in subjects nine years of age and older. Patients had clinical diagnosis of CI and a genetic confirmation of either ARCI-LI (e.g., transglutaminase 1-deficient) or RXLI (e.g., deletion of steroid sulfatase gene) subtypes of CI. Patients had, at baseline, an affected body surface area between a minimum of 10% and maximum of 90% that was treated.

We have analyzed the primary endpoint using a validated tool called the Visual Index of Ichthyosis Severity ("VIIS") that has been shared with the FDA. Common tools used to measure CI severity have either not been validated or if validated have used a very limited number of subjects and few expert graders.

The VIIS is a tool validated and published by Yale researchers for scaling and erythema. It provides detailed written descriptions for both features based on the level of severity, visual standards for 4 body sites (upper back, upper arm, lower leg/shin, and dorsal foot) in CI patients, with two distinct standards that account for different types of scale. Based on the high concordance between expert graders for the scaling score during the VIIS validation process, the primary efficacy endpoint for the proposed Phase 2b study is the change in VIIS scaling score relative to Baseline. The proportion of subjects with treatment success (VIIS-50) is defined as a 50% or greater decrease in the VIIS scaling score relative to baseline at the end of study calculated in patients that have a baseline score of 3 or higher. These patients represent moderate to severe disease phenotype.

On July 1, 2020, we announced that all 11 sites across the United States and Australia in the Phase 2b CONTROL study evaluating TMB-001 in patients with moderate to severe CI were enrolling patients. As of December 31, 2020, all sites participating in a Phase 2b clinical trial evaluating TMB-001 were opened and enrolling patients. On May 31, 2021, we completed patient enrollment in the Phase 2b clinical trial with 34 patients randomized. On October 7, 2021, we announced top line data from the TMB-001 Phase 2b trial. The data demonstrated a reduction in targeted and overall severity of CI in patients treated with topical IPEG™ TMB-001 (topical isotretinoin). Top-line results including descriptive statistics are described below:

- In the per protocol population (the "PP population"), 100 percent (nominal p = 0.04) and 40 percent (nominal p= ns) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved VIIS-50 compared to 40 percent in the vehicle group.

- In the intent to treat (the "ITT") population, 64 percent (nominal p =0.17) and 40 percent (nominal p =ns) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved VIIS-50 compared to 33 percent in the vehicle group.

- In the PP population, 100 percent (nominal p =0.002) and 60 percent (nominal p =ns) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved a ≥2 point improvement in the IGA at week 12 compared to 10 percent in the vehicle group.

- In the ITT population, 55 percent (nominal p =0.02) and 40 percent (nominal p =ns) of patients treated with TMB-001 0.05% and 0.1%, respectively, achieved a ≥2 point improvement in the IGA at week 12 compared to 8 percent in the vehicle group.

- TMB-001 was generally well tolerated with a similar incidence of adverse events (AEs) across treatment groups. The most frequent AEs were local adverse effects common for such topical treatments. There were no treatment-related serious adverse events (SAE).

The key characteristics of the study that we designed included measuring the efficacy of TMB-001 on two scales, the VIIS and the IGA. The VIIS assessed improvements in well-defined, affected areas to allow unambiguous dose selection for the pivotal Phase 3 trial(s) and the IGA provided a broader perspective of the disease severity and therapeutic response. Given the FDA's historical interest in IGA, and in agreement the FDA, Timber also used IGA as key secondary endpoint to determine overall diseases severity at baseline, throughout the study and at the end of the study visit. IGA scores were dichotomized to "treatment success" or "treatment failure" where "treatment success" was defined as at least a 2-grade decrease in severity score relative to baseline at the end of study. The VIIS areas were included in IGA assessment so that concordance between the two end points resulted in further validation of VIIS to be used uniquely in Phase 3 with the added knowledge of its fidelity and reproducibility.

Another key aspect of the Phase 2b study was that emollients and keratolytics were not allowed in the VIIS area, or any other area where the subject was applying the study drug. This could be accomplished because TMB-001 has demonstrated good skin occlusion, hydration and lubrication so that patients did not find the need to use other emollients in the treated areas during the study. This was important as the use of these agents can confound the results

In addition, we intend to generate additional preliminary data to assess the impact of TMB-001 treatment on quality of life of CI patients and generate preliminary data to support clinical meaningfulness of TMB-001 in the lives of CI patients. To that end, an age-appropriate Dermatology Quality of Life Index ("DLQI"), which is a dermatology-specific Quality of Life instrument will be used. Itch is a prominent feature in CI patients, so additionally pruritus was assessed with a self-administered Patient Reported Outcome questionnaire using the I-Numerical Rating Scale ("NRS ") at various visits.

On February 3, 2022, we. announced the successful completion of an End-of-Phase 2 meeting with the FDA that resulted in a clear path to progress to a pivotal Phase 3 study for TMB-001. The clinical development program for TMB-001 includes a Phase 3 study with an efficacy arm and a maximum use pharmacokinetic arm, as well as a smaller bridging study required to bridge to the oral reference product. Based on FDA feedback at the End-of-Phase 2 meeting, we intend to initiate a pivotal Phase 3 study of TMB-001 in mid-2022.

On March 25, 2022, we announced a late-breaking presentation of a sub-analysis of the Company's Phase 2b CONTROL study that evaluated TMB-001, was made by a third party at the American Academy of Dermatology 2022 Annual Meeting. The sub-type analysis found that TMB-001 0.05% demonstrated a substantially greater proportion of patients achieving VIIS-50 and ≥2-grade IGA improvement compared with vehicle regardless of subtype. Among enrolled patients (TMB-001 0.05% [n=11], 0.1% [n=10], and vehicle [n=12]), 55% had ARCI-LI and 45% XLRI subtypes.

Competitive Landscape

There are currently no approved topical isotretinoin products available in the United States. We are currently aware of two other programs that are or were active in the CI space that may compete with the TMB-001 program. The first program in development was the development of trifarotene, a tropical retinoid from Mayne Pharma International Pty. Mayne was conducting a phase 2 randomized, multi-center, double-blind, vehicle controlled, 90 day, safety, efficacy, and systemic exposure study followed by a 90 day open-label extension of trifarotene cream (CD5789) in adults and adolescents with autosomal recessive ichthyosis with lamellar scale. As of September 2021, this study has been terminated for futility (NCT03738800). With the termination of this trial, TMB-001 is the only topical retinoid in development for CI in the United States and assuming a successful Phase 3 program, has the possibility to be a first to market therapy.

The second program in development is from Krystal Biotech, whose product KB105, is currently the subject of an ongoing phase 1/2 clinical trial for the treatment of TGM1-deficient ARCI. KB105, a replication-incompetent, non-integrating HSV-1 vector expressing human transglutaminase 1 (TGM1) formulated as a topical gel. The Phase 1/2 study is an open label, single group, intra-patient comparison of KB105 and placebo-administered target areas. Up to six adult subjects are planned for the Phase I portion of this study. Patients will be evaluated for safety, and target areas will be assessed individually with the IGA and VIIS scales. Target areas will be imaged and evaluated for safety and efficacy. Subjects will be on-trial for approximately 3.5 months. As of September 2021, the trial was active but had not begun recruiting (NCT04047732). It is the belief of management that the TMB-001 program is significantly more advanced the KB105 program in terms of development timelines. We believe that the TMB-001 program has additional key differentiators that we believe to be relevant including: a broader range of disease states being studied (Lamellar Ichthyosis including the TGM1mutations but also other mutations and X-Linked Ichthyosis); a topical formulation versus gene therapy and a known mechanism of action in the disease.

Background of Topical Rapamycin (TMB-002 / Pascomer®)

We are developing a treatment for FAs with our product TMB-002, a topical rapamycin cream. TSC is a rare autosomal dominant inherited neurocutaneous disorder that causes tumors to form in many different organs, usually observed in the brain, eyes, heart, kidney, skin and lungs.

Ongoing Phase 2b Study

A Phase 2b dose-ranging study evaluating the safety and efficacy of 0.5% and 1.0% TMB-002 (Pascomer®) in FAs associated with TSC is currently underway. This Phase 2 multi-center, double-blind, placebo-controlled, randomized, parallel-group study is a dose-response comparison of the efficacy and safety of TMB-002 in male and female patients aged between six years and 65 years.

Eligible patients are diagnosed with TSC based on the clinical diagnostic criteria of the International Tuberous Sclerosis Complex Consensus Conference 2012 and presenting visible FA, with a FA severity score of 2 or 3 on the IGA.

The efficacy and safety assessments are being made at clinical visits, at baseline, through 26 weeks, and at 4 weeks after the last dose of study drug. The primary endpoint of the study is the percentage of patients successfully treated based on investigator blinded assessment using the IGA scale after 26 weeks of treatment. The study includes secondary endpoints of: time from the first dose to IGA success; change in IGA from baseline; change in the Facial Angiofibroma Severity Index ("FASI") from baseline; percentage improvement in FA, as assessed by the participant or parent/caregiver; percentage improvement in the FA severity index ("FASI"), as assessed by the clinician and change in FA on a 5-point scale, as assessed by the participant or parent/caregiver.

The time-to-treatment success will be determined using Kaplan-Meier analyses and compared between each dose group and vehicle. Also, the secondary endpoints will assess change from baseline in IGA after 26 weeks of treatment and change from baseline in FASI after 26 weeks of treatment.

To understand the patients' or caregiver's perception of a therapeutic response, a patient or parent/caregiver's improvement rating assessment from the first visit after the 26 weeks treatment will be determined.

The study is expected to generate data that will enable us to make appropriate dose selection for our Phase 3 studies.

Completed Studies

Since this product development program started, our partner, AFT, has sponsored two in vitro studies and two animal studies. The results of these studies indicate that topical rapamycin cream has an efficient skin absorption and penetrability profile and does not result in irritation upon ocular contact and is not a "contact sensitizer". The long-term toxicity pre-clinical study found that rapamycin creams at concentrations of 0.1%, 1%, and 5% were well tolerated in minipigs and the no-observed-adverse-effect-level was 5%. Mean blood concentrations generally increased with daily application, with increasing cream concentrations but the increases were not consistently dose proportional. The lower strength topical rapamycin formulations (1.0% and 0.5%) are being investigated in the ongoing Phase 2b clinical trial.

Competitive Landscape

Due to the absence of an FDA approved topical rapamycin, drug products containing the molecule is currently being compounded. Pharmacy compounding involves the preparation of customized medications for individual patients with specialized medical needs. Compounded drugs are not generally commercially available and with some exceptions cannot be made until an individual prescription is written. The regulatory oversight of pharmacy compounding is significantly less rigorous than that required for FDA-approved drugs; as such, compounded drugs may pose additional risks to patients. FDA-approved drugs are made and tested in accordance with good manufacturing practice regulations ("GMPs"), which are federal regulations that govern the production and testing of pharmaceutical products. In contrast, compounded drugs are exempt from GMPs, and testing to assess product quality is inconsistent. Unlike FDA-approved drugs, pharmacy-compounded products are not clinically evaluated for safety or efficacy. There are numerous studies that have demonstrated that compounded formulations can suffer from issues related to quality, potency and content uniformity. The cost of compounded rapamycin can also prove prohibitive for some patients.

There are at least two additional topical rapamycin products in development:

Nobelpharma has a topical rapamycin formulation that is approved solely in Japan at a lower strength (0.2%). This product has twelve months of stability at refrigerated conditions and would potentially require significant additional clinical work in Western populations to gain approval in the United States. and Europe.

Aucta Pharma is running a smaller Phase 2 study with a topical rapamycin product. Management believes that TMB-002 is further along in the development process.

Background of Locally Applied Sitaxsentan (TMB-003)

We are developing a treatment for scleroderma with our product TMB-003, locally applied Sitaxsentan. Scleroderma is a chronic connective tissue disease that is generally classified as one of the autoimmune rheumatic diseases.

In-Vitro, Preclinical Studies

Investigative studies of the effects of endothelin receptor selectivity on cutaneous fibrosis and pigmentation were completed in January 2018. Sitaxsentan is a highly selective (6,500:1) endothelin-A ("ET-A") receptor antagonist developed for systemic use but never as a topical agent. Bosentan is a dual endothelin-A / endothelin-B ("ET-B" and together with ET-A, "ET-A/ ET-B") receptor antagonist developed and available for systemic use but not as a topical agent.

The endothelins, ET-1, ET-2 and ET-3, are a group of peptides that act on two distinct receptor subtypes, ET-A and ET-B. Of these three peptides, ET-1 has been the most studied. ET-1 stimulates cardiac contraction and the growth of cardiac muscle cells, regulates the release of substances that affect the blood vessels, stimulates smooth muscle cell division, and may control inflammatory responses by stimulating the production of pro-inflammatory cytokines.

In a series of studies, Sitaxsentan was found to have a significant effect on several important mechanisms of cutaneous fibrosis including its ability to reduce fibroblast migration, induce apoptosis, and reduce the amount of collagen produced. Further, Sitaxsentan outperformed Bosentan in several important mechanisms of cutaneous fibrosis. This is notable in the reduction of the amount of collagen produced in induced cells which can be compared back to un-induced controls. This suggests an inhibition in the development of a pro-fibrotic phenotype. Furthermore, enhanced apoptosis in a pro-fibrotic environment is likely beneficial, as resistance to apoptosis has been reported to be a characteristic of scleroderma fibroblasts. The results suggest that both drugs increase apoptosis compared to the control, whereby Sitaxsentan is more effective than Bosentan in stimulating apoptosis and the clearance of fibrosis-inducing cells. In both scratch assays, Sitaxsentan was superior to Bosentan in preventing closure of the scratch, suggesting that hypermotility and proliferation, characteristic of scleroderma fibroblasts, could be reduced.

Sitaxsentan was also found to decrease the production of melanin, suggesting that it could be useful in treating hyperpigmentation. The effect of Sitaxsentan in in these studies suggest it could be a useful agent in addressing conditions of cutaneous fibrosis and hyperpigmentation through a selective targeting of the Endothelin-A receptors.

Intellectual Property and Market Protection

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for product candidates and any of our future product candidates, novel discoveries, product development technologies and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets, know-how, continuing technological innovation, orphan drug exclusivity and potential in-licensing opportunities to develop and maintain our proprietary position.

As of December 31, 2021, we own or have licensed rights to at least 19 patents or patent applications, including at least 4 U.S. patent applications, and at least 15 international patent applications. All of our current patent applications related to our product candidates currently in development are projected to expire between 2031 and 2038, subject to any PTE that might be available in a particular jurisdiction.

TMB-001	TMB-002	TMB-003
° WO 2017/074982 A1 – Isotretinoin Formulations and Uses and Methods Thereof ° U.S. Patent No. 10,933,018 issued March 2, 2021 ° Patents also granted in Australia, Japan, and China ° Claims were allowed in the USA ° Pending applications and/or further divisional applications in Australia, Canada, China, Japan, EPO, Mexico, South Korea, and USA ° U.S. Divisional Application No. 16/875,710 was filed in 2020 ° Protection through at least 2035 ° Freedom to Operate (FTO) complete ° Expansion planned around dosing, PK, and other methods of use	° AUS 2020277132 – formulation application licensed from AFT, with expansion planned around other methods of use ° Will be converted to PCT and pursued in key countries ° Priority date of November 2020 ° FTO complete	° WO 2019/173215 A1 – Compositions and methods for treating cutaneous fibrosis ° Pending in Australia, Brazil, Canada, China, EPO, Israel, Japan, Korea, and the USA ° Priority date of March 2018 ° WO 2019/173219 – Compositions and methods for treating pigmentation disorders ° Pending in the USA ° Priority date of March 2018 ° Landscape search complete ° Expansion planned around dosing, PK, and other methods of use

While we seek broad coverage under our existing patent applications, there is always a risk that an alteration to the products or processes may provide sufficient basis for a competitor to avoid infringing our patent claims. In addition, patents, if granted, expire and we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any potentially issued patents will adequately protect our products or product candidates.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a period due to delay by the USPTO in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies for our products or processes, or to obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future products may have an adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, please see “Risk Factors—Risks Related to Our Intellectual Property.”

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local levels, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import and export of pharmaceutical products, such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and marketing approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

United States Government Regulations

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the drug development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending new drug applications, or NDAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves:

- Completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug for each indication
- Submission to the FDA of an NDA;
- Satisfactory completion of an FDA advisory committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Satisfactory completion of an FDA inspection of selected clinical sites to assure compliance with GCPs and the integrity of the clinical data;
- Payment of user fees; and
- FDA review and approval of the NDA.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some nonclinical testing may continue even after the IND is submitted. An IND automatically becomes effective and a clinical trial proposed in the IND may begin 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

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

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined. In Phase 1, the drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an initial indication of its effectiveness. In Phase 2, the drug typically is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. In Phase 3, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the safety and efficacy of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor’s agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug. Such post approval trials are typically referred to as Phase 4 clinical trials.

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

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Orphan Drug Pathway

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product in the United States. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, by providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication that could be used “off-label” by physicians in the orphan indication, even though the competitor’s product is not approved in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do of the same product, as defined by the FDA, for the same indication we are seeking, or if our product candidate is determined to be contained within the scope of the competitor’s product for the same indication or disease. If one of our products designated as an orphan drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

Expedited Review and Approval

The FDA has various programs, including fast track designation, breakthrough therapy designation, accelerated approval and priority review, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. The FDA may also review sections of the approval application for a fast-track product on a rolling basis before the complete application is submitted, if the sponsor and the FDA agree on a schedule for the submission of the application sections, and the sponsor pays any required user fees upon submission of the first section of the approval application.

In addition, under the provisions FDASIA, passed in July 2012, a sponsor can request designation of a product candidate as a “breakthrough therapy.” A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on

the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than an irreversible effect on morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a product receiving accelerated approval to perform post-marketing trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation, accelerated approval and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to the FDA because the FDA has sixty days from receipt to make a decision as to whether the application has been accepted for filing.

In addition, under the Pediatric Research Equity Act of 2003 as amended and reauthored, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP requirements.

The testing and approval process for an NDA requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from preclinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval of an NDA on a timely basis, or at all.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Manufacturing and Supply

We contract with third parties for the manufacturing of all of our product candidates, and for pre-clinical and clinical studies and intend to continue to do so in the future. We do not own or operate any manufacturing facilities and we have no plans to build any owned clinical or commercial scale manufacturing capabilities. We believe that the use of contract manufacturing organizations (CMOs) eliminates the need to directly invest in manufacturing facilities, equipment and additional staff. Although we rely on contract manufacturers, our personnel and consultants have extensive manufacturing experience overseeing CMOs.

As we further develop our products, we expect to consider secondary or back-up manufacturers for both active pharmaceutical ingredient and drug product manufacturing. To date, our third-party manufacturers have met the manufacturing requirements for our product candidates in a timely manner. We expect third-party manufacturers to be capable of providing sufficient quantities of our product candidates to meet our current needs, but we have not assessed these capabilities beyond the supply of clinical materials to date. We currently engage CMOs on a ‘‘fee for services’’ basis based on our current development plans.

Environmental, Social and Governance

Management and our Board are committed to corporate responsibility and recognize the importance of environmental, social and governance issues. including hiring, promotion and development practices. Our mission as an organization is to be patient-centric and develop innovative treatments to find solutions for patients suffering from rare and underserved dermatological diseases.

Human Capital

As of December 31, 2021, we had five full-time employees. None of our employees are covered by a collective bargaining agreement, and we consider our employee relations to be satisfactory. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants with the overall goal of having an employee base that embraces teamwork and shares a focus for using each person's individual skills, experience and expertise in order to develop and maximize the value of corporate assets, and

achieve long-term revenue and earnings growth. As we build our organization, we will continue to focus on diversity, equity and inclusion across all aspects of our organization.

Other Information

We file periodic reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information may be obtained, free of charge, by visiting the SEC's website at www.sec.gov that contains all of the reports, proxy and information statements, and other information that we electronically file or furnish to the SEC. We also maintain a website at www.timberpharma.com where we make available the proxy statements, press releases, registration statements and reports on Forms 3, 4, 8-K, 10-K and 10-Q that we (and in the case of Section 16 reports, our insiders) file with the SEC. These forms are made available as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Press releases are also issued via electronic transmission to provide access to our financial and product news, and we provide notification of and access to voice and internet broadcasts of our quarterly and annual results. Our website also includes investor presentations and corporate governance materials.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

- We have a limited operating history and have never generated any product revenue.
- Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.
- Our business is heavily dependent on the successful development, regulatory approval and commercialization of our product candidates.
- Outbreaks of communicable diseases, including the COVID-19 pandemic, and adverse global conditions, including political and economic uncertainty, may materially and adversely affect our business, financial condition and results of operations.
- We will require substantial additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of any of our product candidates.
- We face significant competition from other biotechnology and pharmaceutical companies that currently are targeting medical dermatological indications that we are studying.
- We rely on our license agreement and acquisition agreements to provide rights to certain intellectual property relating to certain of our product candidates and maintenance of our rights under those agreements requires substantial payments.
- If we are unable to establish sales capabilities through third parties, we may not be able to market and sell our existing or future product candidates, if approved, or generate product revenue.
- We rely on our management team and other key employees and will need additional personnel to grow our business.
- Our business is subject to, and may be affected by, government regulation.
- Any failure by us to protect our intellectual property rights or maintain the right to use certain intellectual property may negatively affect our ability to compete.
- Failure to maintain effective internal controls over financial reporting could have a materially adverse effect on our business, operating results and stock price.

- Substantial future sales of shares of our common stock could cause the market price of our common stock to decline.

- Issuance of our common stock upon exercise of convertible securities may depress the price of our common stock.

- If we fail to effectively manage our growth, our business, financial condition and results of operations would be harmed.

Risks Related to Our Business, Financial Position and Capital Requirements

We have a limited operating history and have never generated any product revenue.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in February 2019, and since inception, we have incurred significant net losses. As of December 31, 2021, we had an accumulated deficit of approximately $28.9 million. We have financed our operations in the last two years with approximately $37 million through capital contributions and a bridge loan.

Our ability to generate product revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, our product candidates in development, including TMB-001, TMB-002 and TMB-003. We have never been profitable, have no products approved for commercial sale, and have not generated any product revenue.

Even if we receive regulatory approval for any of our product candidates, we do not know when or if such product candidate will generate product revenue. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete pre-clinical studies and clinical trials and obtain and maintain regulatory approval for the marketing of our product candidates;

- add operational, financial and management information systems personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;

- establish or maintain collaborations, licensing or other arrangements;

- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of our product candidates manufactured at acceptable cost and quality levels and in compliance with the FDA and other regulatory requirements;

- launch commercial sales of our products, whether alone or in collaboration with others, including establishing sales, marketing and distribution systems for our product candidates;

- set an acceptable price for any approved product candidates and obtain coverage and adequate reimbursement from third-party payors;

- achieve market acceptance of our products in the medical community and with third-party payors and consumers;

- compete effectively against our current and future competitors;

- manage the impact of public health issues, including the COVID-19 pandemic and adverse global conditions, including political and economic uncertainty; and

- maintain, expand and protect our intellectual property portfolio.

Because of the numerous risks and uncertainties associated with product development, Timber is unable to predict the timing or amount of increased expenses, or when or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by the FDA or comparable non-U.S. regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if any of our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with their commercial launch. If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be negatively impacted.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or fail to become commercially viable. We have never generated any product revenue, and we cannot estimate with precision the extent of its future losses. We do not currently have any products that are available for commercial sale and we may never generate product revenue or achieve profitability. Our net loss was approximately $10.6 million for the year ended December 31, 2021. As of December 31, 2021, we had an accumulated deficit of approximately $28.9 million.

TMB-001 has not been approved for marketing in the United States and may never receive such approval. Although TMB-001 has an open IND and we are currently in the process of planning our Phase 3 pivotal study, TMB-001 may never receive FDA approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it.

We expect to continue to incur substantial and increasing losses through the commercialization of any of our product candidates, if approved. None of our product candidates have been approved for marketing anywhere in the world, and we may never receive such approval. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to generate product revenue and achieve profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals for such product candidates, and manufacture and successfully market our product candidates alone or in collaboration with others. There can be no assurance that we will be profitable even if we successfully commercialize any of our product candidates. If we do successfully obtain regulatory approval to market any of our product candidates, our revenue will be dependent upon, in part and among other things, the size of the markets in the territories for which it gains regulatory approval, the number of competitors in such markets, the accepted price for any such product candidate and whether we own the commercial rights for those territories. If the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of any of our product candidates, even if approved. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely impact the market price of our common stock and our ability to raise capital and continue operations.

We expect that our research and development expenses in connection with our development programs for our various product candidates will continue to be significant. We also are required to make substantial payments under the agreements under which we acquired our principal intellectual property rights. In addition, as we prepare for and if we obtain regulatory approval for any of our product candidates, we expect to incur increased sales, marketing and manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have harmed and will continue to harm our financial position and working capital.

Our independent registered public accounting firm has issued a going concern opinion on our consolidated financial statements as of December 31, 2021, expressing substantial doubt that we can continue as an ongoing business due to insufficient capital for us to fund our operations.

Our business is heavily dependent on the successful development, regulatory approval and commercialization of our product candidates.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures will be devoted to the continued clinical evaluation and development of our lead product candidates TMB-001, TMB-002 and TMB-003 and the commercialization of such product candidates following regulatory approval, if received, as well as the continued clinical and preclinical evaluation of any of our other product candidates. Accordingly, our business currently depends heavily on the successful completion of our clinical trials and other development activities for our product candidates and subsequent regulatory approval and commercialization of such product candidates.

We cannot be certain that any of our product candidates will receive regulatory approval or be successfully commercialized even if such product candidates receive regulatory approval. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of products are, and will remain, subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries that each have differing regulations. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA or in any foreign country until we receive the requisite approvals from the appropriate authorities in such countries for marketing authorization. In addition, we have not yet demonstrated our ability to complete later-stage or pivotal clinical trials for any of our product candidates.

We have not submitted an NDA for any of our product candidates to the FDA or any comparable application to any other regulatory authority. Obtaining approval of an NDA or similar regulatory approval is an extensive, lengthy, expensive and inherently uncertain process, and the FDA or other foreign regulatory authorities may delay, limit or deny approval of any of our product candidates for many reasons, including:

- We may not be able to demonstrate that any of our product candidates are safe or effective as a treatment for any of our currently targeted indications to the satisfaction of the FDA or other relevant regulatory authorities;
- the relevant regulatory authorities may require additional pre-approval studies or clinical trials which would increase our costs and prolong its development timelines;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or other relevant regulatory authorities for marketing approval;
- the FDA or other relevant regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials, including the design of our future pivotal Phase 3 clinical trials;
- the contract research organizations and other vendors (collectively “CROs”) that we may retain to conduct clinical trials may take actions outside of our control, or otherwise commit errors or breaches of protocols, that adversely impact our clinical trials and ability to obtain market approvals;
- the FDA or other relevant regulatory authorities may not find the data from nonclinical studies or clinical trials sufficient to demonstrate that the clinical and other benefits of these products outweigh their safety risks;
- the FDA or other relevant regulatory authorities may disagree with our interpretation of data or significance of results from the nonclinical studies and clinical trials of any product candidate, or may require that we conduct additional studies;
- the FDA or other relevant regulatory authorities may not accept data generated from our clinical trial sites;
- if our NDA or other foreign application is required to be reviewed by an advisory committee;
- the FDA or other relevant regulatory authority, as the case may be, may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of such

application or may recommend that the FDA or other relevant regulatory authority, as the case may be, require, as a condition of approval, additional nonclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA or other relevant regulatory authorities may require development of a REMS, or its equivalent, as a condition of approval;
- the FDA or other relevant regulatory authorities may require additional post-marketing studies and/or a patient registry, which would be costly;
- the FDA or other relevant regulatory authorities may find the chemistry, manufacturing and controls data supporting our NDA insufficient to support the approval of our product candidates;
- the FDA or other relevant regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers; or
- the FDA or other relevant regulatory authorities may change their approval policies or adopt new regulations.

Even if we do receive regulatory approval to market any product candidate, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that any of our product candidates will be successfully developed or commercialized.

In addition, because each of our product candidates targets one or more indications in the medical dermatology field, if any of our product candidates encounter safety or efficacy problems, developmental delays, regulatory issues, supply issues, or other problems, our development plans for the affected product candidate and some or all of our other product candidates could be significantly harmed, which would harm our business. Further, competitors who are developing products in the dermatology field or that target the same indications as us with products that have a similar mechanism of action may experience problems with its products that could identify problems that would potentially harm our business.

The Company has a class of Series A Preferred Stock which is currently redeemable, subject to Delaware law.

The Company has a class of Series A Preferred Stock, as to which the holder, TardiMed, has demanded redemption. The redemption price is equal to approximately $2.1 million in the aggregate, including accumulated and unpaid dividends which accrue dividends at the rate of 8% per annum. Redemption is subject to certain limitations under Delaware law, so that our ability to effect the redemption demanded by TardiMed is limited in our current financial situation.

Adverse global conditions, including economic uncertainty, may negatively impact our financial results.

Global conditions, dislocations in the financial markets, any negative financial impacts affecting United States corporations operating on a global basis as a result of tax reform or changes to existing trade agreements or tax conventions, or inflation, could adversely impact our business in a number of ways, including longer sales cycles, lower prices for our products, reduced licensing renewals, customer disruption or foreign currency fluctuations.

In addition, the global macroeconomic environment could be negatively affected by, among other things, the COVID-19 pandemic or other epidemics, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of the Ukraine and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

Outbreaks of communicable diseases, including the COVID-19, may materially and adversely affect our business, financial condition and results of operations.

We face risks related to health epidemics or outbreaks of communicable diseases, for example, the recent outbreak around the world, of the highly transmissible and pathogenic COVID-19. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries.

In December 2019, a novel strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China and on March 11, 2020, was declared a pandemic by the World Health Organization. The ultimate impact of the COVID-19 pandemic on our operations is unknown and will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the COVID-19 outbreak, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that governments, or we, may determine are needed.

To date, many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of COVID-19 and have closed non-essential businesses. As local jurisdictions continue to put restrictions in place, our ability to continue to operate our business may also be limited. Such events may result in a period of business, supply and drug product manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. It is also possible that COVID-19 could disproportionately impact the hospitals and clinical sites in which we conduct any of our clinical trials, which could have a material adverse effect on our business and our results of operation and financial condition.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

This pandemic could result in difficulty securing clinical trial site locations, CROs, and/or trial monitors and other critical vendors and consultants supporting the trial. In addition, outbreaks or the perception of an outbreak near a clinical trial site location could impact the Company’s ability to enroll patients. These situations, or others associated with COVID-19, could cause delays in the Company’s clinical trial plans and could increase expected costs, all of which could have a material adverse effect on the Company’s business and its financial condition.

The COVID-19 outbreak may also affect the ability of our staff and the parties we work with to carry out our non-clinical, clinical, and drug manufacturing activities. We rely or may in the future rely on clinical sites, investigators and other study staff, consultants, independent contractors, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our nonclinical studies and clinical trials. We also rely or may in the future rely on consultants, independent contractors, contract manufacturing organizations, and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our active pharmaceutical ingredient production, formulation, and drug manufacturing activities. COVID-19 may affect the ability of any of these external people, organizations, or companies to devote sufficient time and resources to our programs or to travel to perform work for us.

Potential negative impacts of the COVID-19 outbreak on the conduct of current or future clinical studies include delays in gaining feedback from regulatory agencies, starting new clinical studies, and recruiting subjects to studies that are enrolling. The potential negative impacts also include inability to have study visits at study sites, incomplete collection of safety and efficacy data, and higher rates of drop-out of subjects from ongoing studies, delays in site entry of study data into the data base, delays in monitoring of study data because of restricted physical access to study sites, delays in site responses to queries, delays in data-base lock, delays in data analyses, delays in time to top-line data, and delays in completing study reports. New or worsening COVID-19 disruptions or restrictions could have the potential to further negatively impact our non-clinical studies, clinical trials, and drug manufacturing activities.

We will require substantial additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of any of our product candidates.

We expect to spend substantial capital to complete the development of, seek regulatory approvals for and commercialize our lead product candidates, TMB-001, TMB-002 and TMB-003, as well as any of our other product candidates. We will require additional capital to complete the development and potential commercialization of our product candidates. Because the length of time and activities associated with successful development of our product candidates are highly uncertain, we are unable to estimate with certainty the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near-and long-term, will depend on many factors, including, but not limited to:

- the outcome, costs and timing of clinical trial results for our current or future product candidates, including the timing, progress, costs and results of our planned Phase 3 clinical trial of TMB-001 for the treatment of congenital ichthyosis as well as our ongoing Phase 2b clinical trial of TMB-002 for the treatment of facial angiofibromas in tuberous sclerosis complex;

- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;

- the cost of filing, prosecuting, defending and enforcing our patents and other intellectual property rights, the cost of maintaining our intellectual property rights under our current license agreements and acquisition agreements;

- the cost of defending potential intellectual property disputes, including patent infringement actions brought by third parties against us or any of our current or future product candidates;

- the effect of competing market developments;

- the cost and timing of completion of commercial-scale manufacturing activities if any of our products are approved for commercial sale;

- the cost of establishing sales, marketing and distribution capabilities for our products through third parties if approved for commercial sale; and

- the initiation, progress, timing and results of the commercialization of our product candidates, if approved for commercial sale.

We believe that our existing cash will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of calendar year 2022. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We cannot be certain that additional capital will be available on acceptable terms, or at all. 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 any product candidate, or potentially discontinue operations altogether. In addition, attempting to secure additional capital may divert the time and attention of our management from day-to-day activities and harm our product candidate development efforts. Because of the numerous risks and uncertainties associated with the development and potential commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays, operating expenditures and capital requirements associated with our current product development programs.

Our inability to obtain additional financing could adversely affect our ability to continue our drug development programs and could negatively impact the timing of our clinical results.

Our ability to meet our obligations and continue the research and development of our product candidates is dependent on our ability to continue to raise adequate financing. We may not be successful in obtaining such additional financing in the amount required at any time, or for any period, or, if available, that it can be obtained on terms satisfactory to us. In the

event that we are unable to obtain such additional financing, we may be unable to continue our drug development programs and we may have to tailor such programs for our drug candidates based on the amount of funding we raise which could negatively impact the timing of our clinical results. In addition, we could be required to cease our operations.

Raising additional funds by issuing equity securities may cause dilution to existing equity holders, raising additional funds through debt financings may involve restrictive covenants, and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

We expect that significant additional capital will be needed in the future to continue our planned operations. Until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic alliances and license and development agreements or other collaborations. To the extent that we raise additional capital by issuing equity securities, existing equity ownership may experience substantial dilution, and the securities may include preferred shares with liquidation or other preferences that could harm the rights of our securityholders. Additionally, any agreements for future debt or preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, creating liens, redeeming our stock or making investments.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Issuance of our common stock upon exercise of convertible securities may depress the price of our common stock.

As of March 15, 2022, we had 63,696,836 shares of common stock issued and outstanding, outstanding, warrants to purchase 44,282,692 shares of common stock at a weighted average exercise price of $1.31 and outstanding stock options to purchase 2,696,473 shares of common stock at a weighted average exercise price of $1.087 per share. In addition, we have outstanding value appreciation rights convertible into an aggregate of 359,486 shares of common stock. All warrants and stock options are convertible, or exercisable into, one share of common stock. The issuance of shares of our common stock upon the exercise of outstanding convertible securities could result in substantial dilution to our stockholders, which may have a negative effect on the price of our common stock.

Our license agreement and acquisition agreements with AFT and Patagonia obligate us to make certain milestone payments prior to the time in which we will be generating revenue.

We are obligated to pay certain milestone payments to AFT and Patagonia pursuant to their license agreement and acquisition agreements. Zachary Rome, a member of our board of directors and former Executive Vice-President and Chief Operating Officer serves as President of Patagonia and also maintains an ownership interest therein. AFT is entitled to up to $25.5 million of cash milestone payments relating to certain regulatory and commercial achievements of TMB-002, with the first payment of $1.0 million upon the successful completion of a Phase 2b trial where the results of such clinical trial meet the clinical trial's primary clinical endpoints. Patagonia is entitled to up to $27.0 million of cash milestone payments relating to certain regulatory and commercial achievements of TMB-001, with the first being a payment of $4.0 million upon initiation of a Phase 3 pivotal trial, as agreed with the FDA. Patagonia is also entitled to up to $10.25 million of cash milestone payments relating to certain regulatory and commercial achievements of TMB-003, with the first being a one-time payment of $250,000 upon the opening of an IND with the FDA.

Because certain of the milestone payments payable by us to AFT and Patagonia are due upon certain events related to the development and regulatory approval of its product candidates, we will be required to make such payments prior to the time at which we are able to generate revenue, if any, from sales any of our product candidates, if approved. There can be no assurance that we will have the funds necessary to make such payments, or be able to raise such funds when needed, on terms acceptable to us, or at all. Furthermore, if we are forced to raise additional funds, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and

market product candidates that we would otherwise develop and market ourselves. If we are unable to raise additional funds or maintain sufficient liquidity to make our payment obligations if and when they become due, we may be in material breach of our license and acquisition agreements and our counterparties may seek legal action or remedies against us, which would harm our business, financial condition, results of operations and prospects.

Our stock price can be volatile, which increases the risk of litigation, and may result in a significant decline in the value of your investment.

Since the completion of the Merger on May 18, 2020, the market price of our common stock has varied between a high of $6.12 and a low of $0.24. The trading price of our common stock has historically been, and is likely to continue to be, highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose part or all of your investment in our common stock. These factors include, but are not limited to, the following:

- price and volume fluctuations in the overall stock market from time to time;
- changes in the market valuations, stock market prices and trading volumes of similar companies;
- actual or anticipated changes in our net loss or fluctuations in our operating results or in the expectations of securities analysts;
- the issuance of new equity securities pursuant to a future offering, including potential issuances of preferred stock;
- general economic conditions and trends;
- major catastrophic events, including the effects of COVID-19 or possible effects from adverse global conditions, including political and economic uncertainty;
- sales of large blocks of our stock;
- additions or departures of key personnel;
- announcements of new products or technologies, commercial relationships or other events by us or our competitors;
- regulatory developments in the United States and other countries;
- failure of our common stock to maintain their listing on the NYSE American or other national market system;
- potential litigation matters or disputes;
- changes in accounting principles; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Due to the volatility of our stock price, we are currently and may be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention in the future attention and resources from our business.

If we are unable to effectively maintain a system of internal control over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.

We maintain disclosure controls and procedures designed to ensure that we timely report information as specified in the rules and regulations of the SEC. We also maintain a system of internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of the financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Effective internal control over financial reporting is necessary for us to provide reliable reports and prevent fraud. Any failure to address such difficulties encountered in maintaining operation of these internal controls over financial reporting, could harm our operations, decrease the reliability of our financial reporting, and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

We are subject to extensive and costly government regulation.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments, and their respective foreign equivalents. The FDA regulates the research, development, preclinical and nonclinical testing and clinical studies, manufacture, safety, effectiveness, record-keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical products. The FDA regulates small molecule chemical entities as drugs, subject to an NDA under the Federal Food, Drug, and Cosmetic Act (“FDCA”). The FDA applies the same standards for biologics, requiring an IND application, followed by a Biologic License Application, or BLA, prior to licensure. Other products, such as vaccines, are also regulated under the Public Health Service Act. The FDA has conflated the standards for approval of NDAs and BLAs so that it requires the same types of information on safety, effectiveness, and CMCs. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our products. The regulatory review and approval process, which includes preclinical and nonclinical testing and clinical studies of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical studies. We or our collaborators must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical, nonclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product’s safety and efficacy, and in the case of biologics also potency and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product.

Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post-marketing surveillance, and/or may require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, ours collaborators, or our contract manufacturing organizations ("CMOs") fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and/or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications or licenses; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

We do not have, and may never obtain, the regulatory approvals we need to market our product candidates.

Following completion of clinical studies, the results are evaluated and, depending on the outcome, submitted to the FDA in the form of an NDA or BLA in order to obtain FDA approval of the product and authorization to commence commercial marketing. In responding to an NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post-approval study and other commitments or reporting requirements or other restrictions on product distribution, or may deny the application. The FDA has established performance goals for review of NDAs or BLAs: six months for priority applications and ten months for standard applications. However, the FDA is not required to complete its review within these time periods. The timing of final FDA review and action varies greatly but can take years in some cases and may involve the input of an FDA advisory committee of outside experts. Product sales in the United States may commence only when an NDA or BLA is approved.

It is possible that none of our product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, may adversely affect the successful commercialization of any drugs or biologics that we or our partners develop, may impose additional costs on us or our collaborators, may diminish any competitive advantages that we or our partners may attain, and/or may adversely affect our receipt of revenues or royalties.

If we are unable to file for approval of TMB-001 or TMB-002 under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to safety and efficacy in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing NDAs for our product candidates include efforts to minimize the data we will be required to generate in order to obtain marketing approval for its product candidates and therefore reduce the development time. We have held pre-IND meetings with the FDA to discuss, among other things, the regulatory pathways for TMB-001 and TMB-002. The timelines for filing and review of our NDAs for TMB-001 and TMB-002 are based on its plan to submit such NDAs under Section 505(b)(2) of the FDCA, which would enable us to rely in part on data in the public domain or elsewhere. We have not yet filed an NDA under Section 505(b)(2) for any of our product candidates. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents, we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third-party would have 45 days from notification of our certification to initiate an action against us.

In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to such product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of our product candidates. Even if no exclusivity periods apply to our applications under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for any of our product candidates, to conduct substantial new research and development activities beyond those we currently plan to engage in order to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We may not be able to realize a shortened development timeline for our product candidates, and the FDA may not approve an NDA based on our review of the submitted data. If products containing isotretinoin or rapamycin are withdrawn from the market by the FDA for any safety reason, we may not be able to reference such products to support a 505(b)(2) NDA for TMB-001 or TMB-002, respectively, and we may need to fulfill the more extensive requirements of Section 505(b)(1). If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of our lead product candidates.

Even if we are able to commercialize any product candidate that we may develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.

The commercial success of our current or future product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of its product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities (such as Medicare and Medicaid), private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize its products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish and maintain pricing sufficient to realize a meaningful return on its investment.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup its investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues. If the prices for our products, if any, decrease or if governmental and other third-party payors do not provide adequate coverage or reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable non-U.S. regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we may commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We rely on our license agreement and acquisition agreements to provide rights to certain intellectual property relating to certain of our product candidates. Any termination or loss of significant rights under any such agreements would adversely impact our development or commercialization of such product candidates.

We have licensed certain intellectual property relating to certain of its product candidates from AFT Pharmaceuticals Limited, or AFT, through a license agreement. We have acquired the rights to certain intellectual property relating to certain of its product candidates from Patagonia through two acquisition agreements. If, for any reason, our license agreement or acquisition agreements are terminated or we otherwise lose those rights, it would harm our business. In addition to financial obligations, our license agreement imposes on us obligations relating to exclusivity, territorial rights, development, commercialization, funding, payment, diligence, sublicensing, insurance, intellectual property protection and other matters. Our acquisition agreements impose on us obligations and restrictions relating to development, commercialization, funding, sublicensing, non-competition, intellectual property protection, payment and royalties and other matters. If we breach any material obligations, or use the intellectual property licensed to or acquired by us in an unauthorized manner, we may be required to pay damages to our collaborators and such collaborators may have the right to terminate the applicable licenses or rights, as applicable, which would result in us being unable to develop, manufacture and sell one or more of our product candidates, if approved. In addition, under the license agreement, the licensor has the first right to file, prosecute (including any post-grant proceeding) and maintain all licensed patents, and we may not have any control over such actions unless such licensor elects not to exercise our rights.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract highly qualified managerial, scientific and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in the price of the common stock that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. However, we will need to hire additional personnel as we further develop our drug candidates. Competition for skilled personnel in the pharmaceutical industry is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of its management, scientific and medical teams may terminate their employment with us on short notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. Other pharmaceutical companies also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2021, we had five employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from its day-to-day activities, including the additional requirements on management as a public company, and devote a substantial amount of time to managing these growth activities. Our future financial performance, ability to commercialize our product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

We may not be successful in our efforts to identify and acquire or in-license additional product candidates, or to enter into collaborations or strategic alliances for the development and commercialization of any such future product candidates.

We may seek to identify and acquire or in-license novel product candidates in the medical dermatology field. The process by which we identify product candidates may fail to yield product candidates for clinical development for a number of reasons, including those discussed in these risk factors and also:

- potential product candidates may, upon further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance;
- potential product candidates may not be effective in treating their targeted diseases; or
- the acquisition or in-licensing transactions can entail numerous operational and functional risks, including exposure to unknown liabilities, disruption of our business, or incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected acquisition or integration costs.

We may choose to focus our efforts and resources on a potential product candidate that ultimately proves to be unsuccessful. We also cannot be certain that, following an acquisition or in-licensing transaction, we will achieve the revenue or specific net income that justifies such transaction. Further, time and resources spent identifying, acquiring and developing potential product candidates may distract management's attention from Timber's primary business or other development programs. If we are unable to identify and acquire suitable product candidates for clinical development, this would adversely impact our business strategy, our financial position and share price.

In the future, may decide to collaborate with other pharmaceutical companies for the development and potential commercialization of our product candidates in the United States or other countries or territories of the world. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because such product candidates may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, it can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

International expansion of our business exposes us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business outside of the United States.

Part of our business strategy involves potential expansion internationally with third-party collaborators to seek regulatory approval for its product candidates outside the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our collaborators to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;

- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;

- reduced protection for intellectual property rights;

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

- failure to comply with the United States Foreign Corrupt Practices Act, or FCPA, including its books and records provisions and its anti-bribery provisions, the United Kingdom Bribery Act 2010, or U.K. Bribery Act, and similar anti-bribery and anti-corruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, negatively impact our financial condition, results of operations and cash flows.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.

Our computer systems, as well as those of various third parties on which we rely, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidate could be delayed.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our drug candidates.

We face a potential risk of product liability as a result of the clinical testing of our drug candidates and will face much greater risk if we commercialize our drug candidates. For example, we may be sued if any product we develop or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;

- injury to our reputation;

- withdrawal of clinical trial participants;

- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize our drug candidates; and
- a decline in the value of our common stock.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We intend to obtain product liability insurance covering our clinical trials. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we haves no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and it may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses, assets or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses, assets or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to Development, Regulatory Approval and Commercialization

If our studies encounter difficulties or fail to demonstrate safety and efficacy to the satisfaction of the FDA and comparable non-U.S. regulators, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Comparable non-U.S. regulatory authorities impose similar restrictions. We may never receive such approvals. We must complete extensive preclinical development and clinical studies to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete, can fail for many reasons, and is inherently uncertain as to outcome. We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable non-U.S. regulatory authorities for any product candidates.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if (1) we are required to conduct additional clinical studies or other testing of our product candidates beyond the studies and testing that we contemplate, (2) we are unable to successfully complete clinical studies of our product candidates or other testing, (3) the results of these studies or tests are unfavorable, uncertain or are only modestly favorable, or (4) there are unacceptable safety concerns associated with our product candidates, we, in addition to incurring additional costs, may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;

- receive shorter periods of exclusive rights to commercialize our product candidates and experience greater and more competition from products from our competitors;
- obtain approval for indications or patient populations that are not as broad as we intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

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

We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on its current timelines, or at all, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. Enrollment in our clinical trials may be slower than we anticipate, leading to delays in our development timelines. For example, we may face difficulty enrolling or maintaining a sufficient number of patients in our clinical trials due to the existing alternative treatments approved for the treatment of any of our targeted indications, such as topical corticosteroids or topical steroid-free therapies for atopic dermatitis or psoriasis, as patients may decline to enroll or decide to withdraw from our clinical trials due to the risk of receiving placebo. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical sites, the eligibility criteria for the trial and the proportion of patients screened that meets those criteria, our ability to obtain and maintain patient consents, and our ability to successfully complete prerequisite studies before enrolling certain patient populations.

Furthermore, any negative results or new safety signals we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials. Similarly, negative results reported by our competitors about their drug candidates may negatively affect patient recruitment in our clinical trials. Also, marketing authorization of competitors in this same class of drugs may impair our ability to enroll patients into our clinical trials, delaying or potentially preventing it from completing recruitment of one or more of our trials.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates or could render further development impossible. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials, and, while we intend to enter into agreements governing their services, we will be limited in our ability to compel their actual performance.

We may not be able to meet requirements for the chemistry, manufacturing and control of our drug product candidates.

In order to receive approval of our products by the FDA and comparable foreign regulatory authorities, we must show that we and our contract manufacturing partners are able to characterize, control and manufacture our drug products safely and in accordance with regulatory requirements. This includes synthesizing the active ingredient, developing an acceptable formulation, performing tests to adequately characterize the formulated product, documenting a repeatable manufacturing process, and demonstrating that our drug products meet stability requirements. Meeting these chemistry, manufacturing and control (“CMC”) requirements is a complex task that requires specialized expertise. If we are not able to meet the CMC requirements, we may not be successful in getting our products approved.

We face significant competition from other biotechnology and pharmaceutical companies that currently are targeting medical dermatological indications that we are studying, and our operating results will suffer if we fail to compete effectively.

The markets for dermatological therapies are competitive and are characterized by significant technological development and new product introduction. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for our targeted inflammatory and medical dermatological indications. We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies or drugs that become available in the future for the treatment of our target indications that we are studying. If approved, our product candidates may also compete with unregulated, unapproved and off-label treatments. Even if another branded or generic product or an over-the-counter, or OTC, product is less effective than our product candidates, a less effective branded, generic or OTC product may be more quickly adopted by physicians and patients than our competing product candidates based upon cost or convenience. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies to gain a share of some patients' discretionary budgets and for physicians' attention within their clinical practices. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

There are currently no approved topical isotretinoin products available in the United States. We are currently aware of two other programs that are or were active in the CI space that may compete with the TMB-001 program. The first program in development was the development of trifarotene, a tropical retinoid from Mayne Pharma International Pty. Mayne was conducting a phase 2 randomized, multi-center, double-blind, vehicle controlled, 90 day, safety, efficacy, and systemic exposure study followed by a 90 day open-label extension of trifarotene cream (CD5789) in adults and adolescents with autosomal recessive ichthyosis with lamellar scale. As of September 2021, this study has been terminated for futility (NCT03738800). With the termination of this trial, TMB-001 is the only topical retinoid in development for Congenital Ichthyoses in the US and assuming a successful Phase 3 program has the possibility to be a first to market therapy.

The second program in development is from Krystal Biotech, whose product KB105, is currently the subject of an ongoing Phase 1/2 clinical trial for the treatment of TGM1-deficient ARCI. KB105, a replication-incompetent, non-integrating HSV-1 vector expressing human transglutaminase 1 (TGM1) formulated as a topical gel. The Phase 1/2 study is an open label, single group, intra-patient comparison of KB105 and placebo-administered target areas. Up to six adult subjects are planned for the Phase I portion of this study. Patients will be evaluated for safety, and target areas will be assessed individually with the IGA and VIIS scales. Target areas will be imaged and evaluated for safety and efficacy. Subjects will be on-trial for approximately 3.5 months. As of September 2021, the trial was active but had not begun recruiting (NCT04047732). It is the belief of management that the TMB-001 program is significantly more advanced the KB105 program in terms of development timelines. We believe that the TMB-001 program has additional key differentiators that we believe to be relevant including a broader range of disease states being studied (Lamellar Ichthyosis including the TGM1mutations but also other mutations and X-Linked Ichthyosis); a topical formulation versus gene therapy and a known mechanism of action in the disease

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market their products. As a result, we expect to face more competition in these markets than in the United States.

Our ability to compete successfully will depend largely on our ability to:

- develop and commercialize therapies that are competitive with other products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our technologies and product;
- obtain required regulatory approvals, including approvals to market our product candidates in ways that are differentiated from existing and future therapies and OTC products and treatments;
- successfully commercialize our product candidates, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs or OTC treatments would have an adverse impact on our business, financial condition and prospects.

If the market opportunities for our product candidates are smaller than we believe them to be, our revenues may be adversely affected and our business may suffer. Because the target patient populations of our product candidates are small, we must be able to successfully identify patients and capture a significant market share to achieve and maintain profitability.

We focus our research and product development on treatments for orphan dermatology indications. Our projections of both the number of people who have failed other therapies or have limited medical options, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence. The number of patients in the United States and elsewhere may turn out to be lower than expected or may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and business. Additionally, because our target patient populations are small, we will be required to capture a significant market share to achieve and maintain profitability.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. Even if we obtain approval for a product candidate in one country or jurisdiction, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

Prior to obtaining approval to commercialize any of our product candidates in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for a product candidate are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. In order to market any products in any particular jurisdiction, we must establish and comply

with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking regulatory approval could result in difficulties and costs for us and require additional nonclinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We have obtained orphan drug designation for TMB-001, TMB-002 and TMB-003 and may seek additional orphan drug designation for other product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the European Medicines Agency ("EMA") from approving another marketing application for the same indication for that drug during that time period. For a product that obtains orphan drug designation on the basis of a plausible hypothesis that it is clinically superior to the same drug that is already approved for the same indication, in order to obtain orphan drug exclusivity upon approval, clinical superiority of such product to this same drug that is already approved for the same orphan indication must be demonstrated. The exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application with respect to any other product candidate will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes, qualification testing, post-approval clinical data, labeling and promotional activities for such product, will be subject to continual and additional requirements of the FDA and other regulatory authorities.

These requirements include submissions of safety and other post-marketing information, reports, registration and listing requirements, good manufacturing practices, or GMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. Even if marketing approval of our product candidates is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of pharmaceutical products to ensure such products are marketed only for the approved indications and in accordance with the provisions of the approved labeling.

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical studies;
- requirements to institute a REMS to monitor safety of the product post-approval;
- warning letters issued by the FDA or other regulatory authorities;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products, fines, restitution or disgorgement of profits or revenue;
- suspension, revocation or withdrawal of marketing approvals;
- refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

If any of our product candidates receive marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market such drug could be compromised.

Clinical studies of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical studies. Consequently, it is possible that our clinical studies may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of any of our product candidates, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we may be required to recall the drug or change the way the drug is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;

- we could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact the price of our common stock.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as our product candidates would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would harm our business and financial condition.

There are risks associated with scaling up manufacturing to commercial scale. If our contract manufacturers are unable to manufacture our drug candidates on a commercial scale, this could potentially delay regulatory approval and commercialization or materially adversely affect our results of operations.

There are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical problems with process scale-up, process reproducibility, stability issues, and lot consistency. We have limited experience contracting with third parties to manufacture our drug candidates and will need to be able to successfully do so. Even if we obtain regulatory approval for our drug candidates, there is no assurance that our contract manufacturers will be able to manufacture the approved products to specifications acceptable to the FDA or other regulatory authorities, to produce them in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of approved products for commercialization, either on a timely basis or at all, our commercialization efforts would be impaired, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we obtain approval to commercialize any of our products outside of the United States, a variety of risks associated with international operations could harm our business.

If any of our product candidates is approved for commercialization outside of the United States, we expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals and rules governing drug commercialization and manufacturing in foreign countries;
- reduced or no protection of intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign reimbursement, pricing and insurance regimes;
- foreign taxes;
- any foreign partners or collaborators not fulfilling their respective regulatory reporting requirements and any foreign regulatory authorities taking actions with respect to such failures, which would be reportable to the FDA;
- any foreign partners or collaborators not informing us of any new post-marketing safety signals in a timely manner;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential noncompliance with the FCPA, the U.K. Bribery Act or similar anti-bribery and anticorruption laws in other jurisdictions;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Legislative and regulatory changes may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drug candidates. In particular, legislative and regulatory proposals have been made to reduce government reimbursements for drugs, expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

Both Congress and the Centers for Medicare & Medicaid Services ("CMS"), the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. There have been legislative proposals to repeal the ‘non-interference" provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors.

The 21st Century Cures Act made changes to the FDA approval process for drugs and medical devices. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Our business also may be affected by legislative and regulatory changes at the state and local level. For example, several states have adopted or are considering adopting laws that require reporting of payments to healthcare professionals and/or require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and

state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce its profitability.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We may seek fast track designation for our product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate us eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if we believe that the designation is no longer supported by data from our clinical development program.

We may seek rare pediatric disease designation for TMB-003 for the treatment of moderate to severe scleroderma; however, an NDA for TMB-003, if approved, may not meet the eligibility criteria for a priority review voucher.

We may seek rare pediatric disease designation for TMB-003 for the treatment of scleroderma. Designation of a drug as a drug for a rare pediatric disease does not guarantee that an NDA for such drug will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the FDCA, we will need to request a rare pediatric disease priority review voucher in our NDA for TMB-003. The FDA may determine that an NDA for TMB-003, if approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- moderate to severe scleroderma no longer meets the definition of a rare pediatric disease;
- the NDA contains an active ingredient (including any ester or salt of the active ingredient) that has been previously approved in an NDA;
- the NDA is not deemed eligible for priority review;
- the NDA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (that is, if the NDA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or
- the NDA is approved for a different adult indication than the rare pediatric disease for which TMB-003 is designated.

The authority for the FDA to award rare pediatric disease priority review vouchers for drugs that have received rare pediatric disease designation prior to September 30, 2020 currently expires on September 30, 2022. If an NDA for TMB-003 is not be approved prior to September 30, 2022, regardless of whether it meets the criteria for a rare pediatric disease priority review voucher, it will not be eligible for a priority review voucher. However, it is also possible the authority for FDA to award rare pediatric disease priority review vouchers will be further extended through Federal lawmaking.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies.

We currently rely on CROs to conduct our clinical studies. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct its clinical studies. Our agreements with these third parties generally allow the third-party to terminate the agreement at any time. If we are required to enter into alternative arrangements because of any such termination the introduction of our product candidates to market could be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we design our clinical studies and will remain responsible for ensuring that each of our clinical studies are conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with cGCPs for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of study participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. We are also required to register ongoing clinical studies and post the results of completed clinical studies on a government-sponsored database, Clinicaltrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical studies. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We may seek to enter into collaborations with third parties for the development and commercialization of its product candidates. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

We may seek third-party collaborators for development and commercialization of our product candidates. Our likely collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, non-profit organizations, government agencies, and biotechnology companies. We are currently party to a limited number of such arrangements and have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving its product candidates currently pose, and will continue to pose, the following risks to it:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical or clinical study results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study or abandon a product candidate, repeat or conduct new clinical studies or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate its intellectual property or proprietary information or expose it to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose it to litigation and potential liability;

- disputes may arise between the collaborators and it that result in the delay or termination of the research, development or commercialization of its product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical studies or clinical studies, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidates, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to its ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidates. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of our product candidates, reduce or delay our development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and

undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on obtaining and maintaining additional patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable in our pending applications or, the enforceability of our existing and future patents.

The degree of our current and future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies, such as trifarotene and KB105 as described above, that are similar or competitive to our product candidates, or important to our business. We cannot be certain that any patents or patent application owned by a third party will not have priority over patents and patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to maintain or obtain additional patent protection or trade secret protection for our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

If we fail to obtain or maintain patent protection or trade secret protection for our technologies, third parties could use our proprietary information, which could impair its ability to compete in the market and adversely affect its ability to generate revenues and attain profitability.

We may also develop trademarks to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

We have in-licensed and acquired portions of our intellectual property, and if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor and/or seller of such intellectual property.

We are a party to a license agreement with AFT pursuant to which we licensed certain exclusive and co-exclusive rights to develop, manufacture and market drug candidates from AFT in certain territories. We have also entered into two acquisition agreements with Patagonia pursuant to which we acquired rights to certain intellectual property worldwide. These agreements are important to our business, and we may enter into additional license and acquisition agreements in the future. Certain of our in-licensed and acquired intellectual property covers, or may cover, other potential developmental candidates. Our existing license agreement and acquisition agreements impose, and we expect that future agreements will impose, various milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our collaborators regarding our rights or obligations under such agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our collaborators may have a right to terminate the affected license or rights, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of our product candidates. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to its product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market our product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that it could redesign any of our product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing any of our product candidates, which could harm our business, financial condition and operating results.

A number of companies have conducted research on dermatological therapies which resulted in the filing of many patent applications related to this research. If we were to challenge the validity of these or any issued United States patent in

court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims.

If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the USPTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

We may be subject to claims challenging the inventorship of its patents and other intellectual property.

Although we are not aware of any asserted third-party claims challenging inventorship on our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, strategic partners, commercial counterparties or other third parties associated with us or one of our predecessors in ownership of our product candidates have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we cannot fully control the enforcement of these policies by third parties with which we contract, nor can we be certain that assignment agreements between us and our employees, between us and our counterparties, or between our counterparties and their employees or between our predecessors of ownership and their employees and counterparties, will effectively protect our interests as to any party who conceives or develops intellectual property that we regard as our own. Among other issues, the assignment of intellectual property rights may not be self-executing, the assignment agreements may be breached, or we may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. As we approach potential commercialization of our product candidates, we are more closely analyzing all facts that we believe might be used to assert an inventorship claim against us. Determinations like these involve complex sets of fact and applications of sometimes-unsettled patent law, resulting in inherent uncertainties regarding ownership rights. Determining the history of development of certain of our intellectual property is made more difficult by the fact that certain of our intellectual property was developed by other companies for other indications before being acquired by us. Consequently, we cannot be sure that we have all of the documentary records relevant to such an analysis.

If claims challenging inventorship are made against us, we may need to resort to litigation to resolve those claims. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of valuable intellectual property rights or the right to assert those rights against third-parties marketing competing products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms. Such a license may not be available, or it may not be available on commercially reasonable terms, in which case our business would be harmed.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could harm our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has recently enacted and implemented wide-ranging patent reform legislation. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and pending patent applications. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects.

There are risks to our intellectual property based on our international business operations.

There are risks to technology and intellectual property that may result from us conducting business outside the United States, particularly in jurisdictions that do not have comparable levels of protection of corporate proprietary information and assets such as intellectual property, trademarks, trade secrets, know-how and customer information and records. For instance, we may be exposed to material risks of theft of proprietary technology and other intellectual property, including technical data, business processes, data sets or other sensitive information. While these risks are common to many companies, conducting business in certain foreign jurisdictions, housing technology, data and intellectual property abroad, or licensing technology to joint ventures with foreign partners may have more significant exposure. The risk can be by direct intrusion wherein technology and intellectual property is stolen or compromised through direct intrusion including cyber intrusions and physical theft through corporate espionage, including with the assistance of insiders. In addition, our technology and intellectual property may be subject to theft or compromise via more indirect routes. For example, our products or components may be reverse engineered by joint venture partners or other parties, which could result in our patents being infringed or our know-how or trade secrets stolen.

We are a “smaller reporting company” and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a “smaller reporting company,” meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a “smaller reporting company,” and have either: (i) a public float of less than $250 million or (ii) annual revenues of less than $100 million during the most recently completed fiscal year and (A) no public float or (B) a public float of less than $700 million. As a “smaller reporting company,” we

are subject to lesser disclosure obligations in our SEC filings compared to other issuers, including being able to provide simplified executive compensation disclosures in our filings and only being required to provide two years of audited consolidated financial statements in our annual reports. In addition, because our public float is less than $75 million, we are a “non-accelerated filer” under Rule 12b-2 of the Exchange Act and are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting. Until such time as we cease to be a “smaller reporting company” or a “non-accelerated filer,” as applicable, such decreased disclosure in our SEC filings may make it harder for investors to analyze our operating results and financial prospects.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease a 3,127 square foot office space at 110 Allen Road, Suite 401, Basking Ridge, New Jersey. Pursuant to the lease agreement entered into on March 10, 2021, this lease expires in March 2023.

We also lease an 11,793 square foot office and laboratory space at 115 Nicholson Lane, San Jose, California 95134. This lease expires in December 2023. On February 17, 2020, we executed a sublease agreement covering the entire space for the remaining term of the lease.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any legal or governmental regulatory proceedings, nor is our management aware of any pending or threatened legal or government regulatory proceedings proposed to be initiated against us that would have a material adverse effect on our business, financial condition or operating results.

From time to time, we could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, we review the status of significant matters, if any exist, and assess our potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, we accrue a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict; therefore, accruals are based on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on the NYSE American under the symbol “TMBR.”

As of March 15, 2022, there were approximately 29 registered holders of record of our common shares, based upon information received from our stock transfer agent. However, this number does not include beneficial owners whose shares were held of record by nominees, including broker dealers. We believe that there are a significantly larger number of beneficial owners of our common shares than the number of record holders.

Unregistered Sales of Equity Securities

None.

Equity Compensation Plan Information

The following table includes information as of December 31, 2021 for our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, and Rights	Weighted-average exercise price of outstanding options, and Rights	Number of securities remaining available for future issuance under equity compensation plans (2)
Equity compensation plans approved by security holders (1)	2,712,254	$ 1.087	1,971,846
Equity compensation plans not approved by security holders (3)	359,486	0.01	—
Total	3,071,740		1,971,846

(1) The amounts shown in this row include (i) 2,696,473 shares underlying options issued under the Plan with a weighted average exercise price of $1.087 and (ii) 15,781 shares of common stock underlying legacy BioPharmX options issued under the 2014 Equity Incentive Plan and the 2016 Equity Incentive Plan with a weighted average exercise price of $75.27.

(2) In accordance with the “evergreen” provision in the Plan, an additional 2,551,846 shares of our common stock were automatically made available for issuance on the first day of 2022, which represents 4% of the number of shares of common stock outstanding on December 31, 2021; these shares are excluded from this calculation.

(3) Includes 359,486 shares of common stock underlying VARs.

ITEM 6. [RESERVED]

Not applicable.

ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management’s Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is intended to help the reader understand our results of operations and financial condition. MD&A is provided as a supplement to, and should be read in conjunction with, our audited consolidated financial statements and the accompanying notes to the consolidated financial statements and other disclosures included in this Annual Report on Form 10-K. Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and are presented in U.S. dollars.

General

Management's discussion and analysis of results of operations and financial condition is intended to assist the reader in understanding and assessing significant changes and trends related to the results of operations and financial position of our Company. This discussion and analysis should be read in conjunction with Item 8, "Financial Statements and Supplementary Data." Certain statements in this Item 7 constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors," may cause our actual results, financial position, and cash used in operations to differ materially from these forward-looking statements

Timber Pharmaceuticals, Inc. (“Timber”, the “Company”, “we”, “us”) is a clinical-stage biopharmaceutical company focused on the development and commercialization of treatments for orphan dermatologic diseases. Our investigational therapies have proven mechanisms-of-action backed by decades of clinical experience and well-established CMC

(chemistry, manufacturing and control) and safety profiles. We are initially focused on developing non-systemic treatments for rare dermatologic diseases including congenital ichthyosis ("CI"), facial angiofibromas ("FAs") in tuberous sclerosis complex ("TSC"), and sclerotic skin diseases. Our lead mid to late-stage programs are TMB-001 and TMB-002. TMB-003 is our earliest stage program.

TMB-001, a patented topical formulation of isotretinoin using our patented IPEG™ delivery system, has completed its Phase 2b clinical trial for the treatment of moderate to severe subtypes of CI, a group of rare genetic keratinization disorders that lead to dry, thickened, and scaling skin, in Q4 2021. This study demonstrated clinically meaningful reduction in targeted and overall severity of CI along with a favorable safety profile. A prior Phase 1/2 study involving 19 patients with CI demonstrated safety and a signal of preliminary efficacy of TMB-001, as well as minimal systemic absorption. A prior Phase 1/2 study involving 19 patients with CI demonstrated safety and preliminary efficacy of TMB-001, as well as minimal systemic absorption.

TMB-002, a proprietary topical formulation of rapamycin, is currently being evaluated in a Phase 2b clinical trial for the treatment of FAs in TSC, a multisystem genetic disorder resulting in the growth of hamartomas in multiple organs. TSC results from dysregulation in the mTOR pathway, and as a topical mTOR inhibitor, TMB-002 may address FAs in TSC without the systemic absorption of an oral agent.

The product in its earliest stage in our pipeline is TMB-003, a proprietary formulation of Sitaxsentan, a new chemical entity in the U.S., which is a selective endothelin-A receptor antagonist. It is currently in preclinical development as a locally applied formulation for the treatment of sclerotic skin diseases. The two disease areas under consideration include: Lichen Sclerosis and Localized Scleroderma.

In connection with the Merger (as defined below), we acquired the BPX-01 and BPX-04 assets. BPX-01 is a Phase 3 ready topical minocycline for the treatment of inflammatory lesions of acne vulgaris, and BPX-04 is a Phase 3 ready topical minocycline for the treatment of papulopustular rosacea. We are seeking to monetize these assets through a license, co-development, or sale.

On May 18, 2020, BioPharmX Corporation ("BioPharmX") completed its business combination with Timber Pharmaceuticals LLC, a Delaware limited liability company ("Timber Sub"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of January 28, 2020 (the "Merger Agreement"), by and among BioPharmX, Timber Sub and BITI Merger, Inc., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"), as amended by Amendment No. 1 thereto made and entered into as of March 24, 2020 (the "First Amendment") and Amendment No. 2 thereto made and entered into as of April 27, 2020 (the "Second Amendment") (the Merger Agreement, as amended by the First Amendment and the Second Amendment, the "Amended Merger Agreement"), pursuant to which Merger Sub merged with and into Timber Sub, with Timber Sub surviving as a wholly-owned subsidiary of the Company (the "Merger"). In connection with, and immediately prior to the completion of, the Merger, BioPharmX effected a reverse stock split of the Company's common stock, par value $0.001 per share (the "Common Stock"), at a ratio of 1-for-12 (the "Reverse Stock Split"). Immediately after completion of the Merger, BioPharmX changed its name to "Timber Pharmaceuticals, Inc." and the officers and directors of Timber Sub became the officers and directors of the Company.

Under the terms of the Amended Merger Agreement, BioPharmX issued shares of Common Stock to the holders of common units of Timber Sub. Immediately after the Merger, there were approximately 11,849,031 shares of Common Stock outstanding (after the Reverse Stock Split). Pursuant to the terms of the Amended Merger Agreement, the former holders of common units of Timber Sub (including the Investors, as defined below, but excluding VARs, as defined below) owned in the aggregate approximately 88.5% of the outstanding Common Stock, with the Company's stockholders immediately prior to the Merger owning approximately 11.5% of the outstanding Common Stock. The number of shares of Common Stock issued to the holders of common units of Timber Sub for each common unit of Timber Sub outstanding immediately prior to the Merger was calculated using an exchange ratio of approximately 629.57 shares of Common Stock for each Timber Sub unit. In addition, the 584 Value Appreciation Rights of Timber Sub ("VARs") that were outstanding immediately prior to Merger became denoted and payable in 367,670 shares of Common Stock at the effective time of the Merger (the "Effective Time"). Further, the holder of the 1,819,289 preferred units of Timber Sub outstanding immediately

prior to the Merger received 1,819 shares of the newly created convertible Series A preferred stock (the "Series A Preferred Stock") at the Effective Time.

In connection with the Merger Agreement, on March 27, 2020, Timber Sub and BioPharmX entered into a securities purchase agreement (the "Securities Purchase Agreement"), with certain accredited investors (the "Investors") pursuant to which, among other things, Timber Sub issued to the Investors shares of Timber units immediately prior to the Merger and BioPharmX issued to the Investors warrants to purchase shares of BioPharmX common stock on the tenth trading day following the consummation of the Merger (the "Investor Warrants") in a private placement transaction for an aggregate purchase price of approximately $25 million (which amount is comprised of (x) a $5 million credit with respect to the Bridge Notes and (y) $20 million in cash from the Investors) (the "Purchase Price"). We issued to the Investors 8,384,764 Series A Warrants to purchase shares of Common Stock ("Series A Warrants") and 7,042,175 Series B Warrants to purchase shares of Common Stock ("Series B Warrants"). The Series A Warrants have a 5-year term and an exercise price of $2.7953, subject to the number of shares and exercise price being reset based on our stock price after the Merger. The Series A Warrants were initially exercisable into 8,384,764 shares of Common Stock issued to the Investors, subject to certain adjustments. The Series B Warrants had an exercise price per share of $0.001, were exercisable upon issuance and were initially convertible into 7,042,175 shares of Common Stock in the aggregate.

In addition, pursuant to the terms of the Securities Purchase Agreement, on May 22, 2020 we issued to the Investors warrants to purchase 413,751 shares of Common Stock (the "Bridge Warrants") which had an exercise price of $2.2362 per share, which was revised to $0.31 per share as a result of the November 2021 Offering.

On November 19, 2020 the Company entered into a Warrant Waiver Agreement with each of the warrant holders which modified the terms of the original agreement and eliminated further resets. The aggregate number of Series A Warrants issued was fixed at 20,178,214 and the warrant exercise price was fixed at $1.16. The aggregate number of Series B Warrants was fixed at 22,766,777. The exercise price of the Series B Warrants remained unchanged.

In addition, certain restrictions contained in the Warrant Agreement and Securities Purchase Agreement were modified including restrictions on the Company's ability to issue additional equity securities in connection with a financing and the Company's ability to complete a fundamental transaction. Subject to certain restrictions detailed in the Warrant Waiver Agreement, the Company is now able to complete an equity financing or a fundamental transaction at any time after April 30, 2021. However, the Company remains restricted with respect to conducting variable rate transactions until May 18, 2023.

Further, in connection with the Warrant Waiver Agreement the Company agreed to immediately register 11,383,389 shares of common stock issuable upon exercise of the Series B Warrants. The warrant holders have additional demand registration rights as described in the Warrant Waiver Agreement. As of March 4, 2021, the Series B Warrants were exercised in full. As of December 31, 2021, 16,701,824 shares of common stock remain issuable upon exercise of the Series A Warrants.

We have a limited operating history as the Company was formed on February 26, 2019. Since inception, Timber's operations have focused on establishing its intellectual property portfolio, including acquiring rights to the proprietary formulations of isotretinoin, rapamycin and Sitaxsentan, as described above, organizing and staffing the Company, business planning, raising capital, and conducting clinical trials. We have financed our operations with $33.3 million through capital contributions over the past two years.

Since inception, we have incurred significant operating losses. For the year ended December 31, 2021, our net loss was $10.6 million. As of December 31, 2021, we had an accumulated deficit of approximately $28.9 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we continue to develop the pipeline of programs.

Recent Developments

TMB-001 Patents

On March 2, 2021, we were granted a patent (US Patent No. 10,933,018) for TMB-001.

On February 8, 2022, we submitted a request to register a further pending Chinese divisional patent application (No. 202110920456.X) in Hong Kong.

Officer Resignation

On March 4, 2022, Zachary Rome stepped down from his positions as the Chief Operating Officer and Executive Vice-President of the Company. As a result of his resignation, Mr. Rome (i) is entitled to 79,326 shares of common stock underlying vested VARs, or $22,528, at the Company's election, and (ii) forfeited 52,884 VARs. Mr. Rome continues to serve on the Company's board of directors.

November 2021 Offering

On November 2, 2021, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC, as representative of the several underwriters named in Schedule I thereto, relating to the public offering, issuance and sale of shares of our common stock and, to certain investors, pre-funded warrants to purchase shares of common stock, and accompanying warrants to purchase shares of our common stock. After giving effect to the sale of additional shares pursuant to the exercise of the option by H.C. Wainwright & Co., LLC that closed on November 9, 2021, the total number of shares of common stock (or common stock equivalents) sold by us in the offering was 26,953,125, together with warrants to purchase up to 26,953,125 shares of common stock issued at the closing on November 5, 2021, for total gross proceeds of $17.25 million before deducting underwriting discounts and commissions and other offering expenses, and net proceeds of approximately $15.8 million. As a result of the offering, the exercise price of the Bridge Warrants was adjusted to $0.31 per share.

Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a warrant to purchase one share of common stock. All the securities sold in the offering were sold by the Company. The public offering price of each share of common stock and accompanying common warrant was $0.64 and $0.639 for each pre-funded warrant and accompanying common warrant. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of common stock and were exercised in full on November 5, 2021. The warrants were immediately exercisable at a price of $0.70 per share of common stock and expire five years from the date of issuance.

Asset Purchase Agreements with Patagonia Pharmaceuticals LLC ("Patagonia")

On February 28, 2019, we acquired the intellectual property rights for a topical formulation of isotretinoin for the treatment of CI and identified as TMB-001, formerly PAT-001 including the IPEG™ brand, from Patagonia (the "TMB-001 Acquisition"). Zachary Rome, a member of our board of directors and our former Executive Vice-President and Chief Operating Officer serves as President of Patagonia and also maintains an ownership interest therein.

Under the terms of the TMB-001 Acquisition, we paid a one-time upfront payment of $50,000 to Patagonia. Patagonia is entitled to up to $27.0 million of cash milestone payments relating to certain regulatory and commercial achievements of the TMB-001 Acquisition, with the first being $4.0 million from the initiation of a Phase 3 pivotal trial, as agreed with the FDA. In addition, Patagonia is entitled to net sales earn-out payments ranging from low single digits to mid-double digits for the program licensed. We are responsible for all development activities under the license. The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 or 2020, respectively.

On June 26, 2019, we acquired the intellectual property rights for a locally administered formulation of Sitaxsentan for the treatment of cutaneous fibrosis and/or pigmentation disorders, and identified as TMB-003, formerly PAT-S03, from Patagonia (the "TMB-003 Acquisition").

Upon closing of the TMB-003 Acquisition, we paid a one-time upfront payment of $20,000 to Patagonia. Patagonia is entitled to up to $10.25 million of cash milestone payments subject to adjustments relating to certain regulatory and commercial achievements of TMB-003, with the first being a one-time payment of $250,000 upon the opening of an investigational new drug ("IND") with the FDA. In addition, Patagonia is entitled to net sales earn-out payments ranging from low to mid-single digits for the program licensed. We are responsible for all development activities under the license.

The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 or 2020, respectively.

Acquisition of License from AFT Pharmaceuticals Limited ("AFT")

On July 5, 2019, we entered into a license agreement with AFT which provides us with (i) an exclusive license to certain licensed patents, licensed know-how and AFT trademarks to commercialize the Pascomer® product in the United States, Canada and Mexico and (ii) a co-exclusive license to develop the Pascomer® product in this territory. Concurrently, we granted to AFT an exclusive license to commercialize the Pascomer® product outside of its territory and co-exclusive sublicense to develop and manufacture the licensed product for commercialization outside of its territory (the "AFT License Agreement").

The AFT License Agreement also provides for the formation of a joint steering committee to oversee, coordinate and review recommendations and approve decisions with respect to the matters related to the development and commercialization of Pascomer® , in which both the Company and AFT have the right to appoint two members. The committee is currently comprised of three members. We have final decision-making authority on all matters relating to the commercialization of Pascomer® pin the specified territory and on all matters related to the development (and regulatory approval) of Pascomer®, with certain exceptions.

The development of Pascomer® is being conducted pursuant to a written development plan, written by AFT and approved by the joint steering committee, which is reviewed on at least an annual basis. AFT shall perform clinical trials of Pascomer® in the specified territory and shall perform all CMC (chemistry, manufacturing and controls) and related activities to support regulatory approval. We are responsible for all expenses incurred by AFT during the term of the AFT License Agreement and shall equally share all costs and expenses with AFT, incurred by AFT for development and marketing work performed in furtherance of regulatory approval and commercialization worldwide, outside of the specified territory. We are also entitled to receive a significant percentage of the economics (royalties and milestones) in any licensing transaction that AFT executes outside of North America, Australia, New Zealand, and Southeast Asia.

Upon closing of the AFT License Agreement, we were obligated to reimburse AFT for previously spent development costs, subject to certain limitations and were obligated to pay a one-time, irrevocable and non-creditable upfront payment to AFT, payable in scheduled installments. AFT is entitled to up to $25.5 million of cash milestone payments relating to certain regulatory and commercial achievements of TMB-002, with the first payment of $1.0 million upon the successful completion of a Phase 2b trial where the results of such clinical trial meet the clinical trial's primary clinical endpoints. In addition, AFT is entitled to net sales royalties ranging from high single digits to low double digits for the program licensed. The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 or 2020, respectively.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

	Year Ended December 31,			
	2021	2020	Change $	Change %
Grant revenue	$ 590,794	$ 453,810	$ 136,984	30 %
Milestone revenue	295,738	—	295,738	N/A %
Total revenue	886,532	453,810	432,722	95 %
Research and development	6,149,586	2,733,026	3,416,560	125 %
Research and development - license acquired	—	12,371,332	(12,371,332)	(100)%
Transaction costs	—	1,501,133	(1,501,133)	(100)%
Selling, general and administrative	5,387,164	4,060,186	1,326,978	33 %
Loss from operations	(10,650,218)	(20,211,867)	9,561,649	(47)%
Interest expense	(15,551)	(4,416,746)	4,401,195	(100)%
Interest income	—	816,657	(816,657)	(100)%
Change in fair value of investment in BioPharmX	—	559,805	(559,805)	(100)%
Change in fair value of warrant liability	—	8,156,770	(8,156,770)	(100)%
Gain (loss) on foreign currency exchange	(3,619)	15,609	(19,228)	(123)%
Net loss before provision for income taxes	**(10,669,388)**	**(15,079,772)**	**4,410,384**	(29)%
(Benefit) provision for income taxes	(30,242)	37,842	(68,084)	(180)%
Net loss	**(10,639,146)**	**(15,117,614)**	**4,478,468**	(30)%
Accrued dividend on preferred stock units	—	(52,669)	52,669	(100)%
Cumulative dividends on Series A preferred stock	(129,992)	(90,516)	(39,476)	44 %
Net loss attributable to common stockholders	**$ (10,769,138)**	**$ (15,260,799)**	**$ 4,491,661**	(29)%

Revenues

For the year ended December 31, 2021, grant revenue was approximately $0.6 million compared to $0.5 million for the year ended December 31, 2020. The increase in revenue of approximately $0.1 million consisted of reimbursements received from the FDA as a result of achieving certain clinical milestones in the development of TMB-001. In September 2018, Patagonia was awarded a $1.5 million grant (the “Grant”) from the FDA as part of the Orphan Products Clinical Trials Grants Program of the Office of Orphan Products Development. The Grant funds were made available in three annual installments of $500,000 per year, which commenced in September 2018. The Grant was transferred to Timber pursuant to its TMB-001 Acquisition Agreement with Patagonia in February 2019. In March 2020 and March 2021, the FDA awarded us the second and third tranches of the grant, respectively.

Milestone revenue for the year ended December 31, 2021, was approximately $0.3 million. These revenues were related to an upfront milestone payment paid to AFT by Desitin to which Timber was entitled under the terms of the AFT License Agreement.

Operating Costs and Expenses

Research and Development Expense

For the year ended December 31, 2021, research and development expenses were $6.1 million compared to $2.7 million for the year ended December 31, 2020. The increase of $3.4 million is primarily related to increased costs incurred related to our Phase 2b and Phase 2a clinical trials of TMB-001 and TMB-002, respectively, such as CRO direct and pass-through expenses and the hire of a new Chief Medical Officer.

Research and development costs were primarily attributable to costs incurred in connection with our research activities and include costs associated with clinical trials, consultants, clinical trial materials, regulatory filings, facilities, laboratory expenses and other supplies.

Research and development costs are expensed as incurred. Costs for certain activities, such as preclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators.

Research and Development Expense - License Acquired

For the year ended December 31, 2020, research and development expense – license acquired was $12.4 million related to our acquisition of BioPharmX. There were no acquired licenses for the year ended December 31, 2021.

Transaction Costs

For the year ended December 31, 2020, transaction costs were $1.5 million consisting of legal and professional fees related to our acquisition of BioPharmX. There were no acquisition transaction costs for the year ended December 31, 2021.

General and Administrative Expense

For the year ended December 31, 2021, general and administrative expenses were $5.4 million compared to $4.1. million for the year ended December 31, 2020. The increase in general and administrative expenses of approximately $1.3 million was due to increased personnel and related costs including stock-based compensation of $0.4. million and increased in salary and benefits expense of $0.6 million due to increased headcount and other overhead expenses of $0.3 million of increased insurance costs of approximately $0.2 million.

Other Income (Expense)

Interest Expense

Interest expense was $0.02 million for the year ended December 31, 2021, which was due to interest charged for the Redeemable Series A convertible preferred stock under redemption, which started in November 2021. For the year ended December 31, 2020, interest expense was $4.4 million due to the amortization of the original issue discount related to the Bridge Notes.

Interest Income

For the year ended December 31, 2020, the interest income was $0.8 million due to the accrued interest and amortization of the OID related to the BioPharmX loan. There was no interest income in 2021.

Change in Fair Value of BioPharmX

For the year ended December 31, 2020, the change in fair value of investment in BioPharmX resulted in a gain of $0.6 million.

Change in Fair Value of Warrant Liability

For the year ended December 31, 2020, the change in fair value of warrant liability resulted in an unrealized gain of $8.2 million due to the decrease in share price during the period.

Comparison of the Quarters Ended December 31, 2021 and 2020

	Three Months Ended December 31, 2021	2020	Change $	Change %
Grant revenue	$ 190,005	$ 102,382	$ 87,623	86 %
Milestone revenue	—	—	—	N/A
Total revenue	190,005	102,382	87,623	86 %
Research and development	1,525,775	493,399	1,032,376	209 %
Selling, general and administrative	1,475,452	1,314,478	160,974	12 %
Loss from operations	(2,811,222)	(1,705,495)	(1,105,727)	65 %
Interest Expense	(15,551)	—	(15,551)	100 %
Change in fair value of warrant liability	—	2,549,477	(2,549,477)	(100)%
Gain (loss) on foreign currency exchange	(3,075)	3,958	(7,033)	(178)%
Net (loss) income before provision for income taxes	**(2,829,848)**	**847,940**	**(3,677,788)**	(434)%
(Benefit) Provision for income taxes	(30,242)	37,842	(68,084)	(180)%
Net (loss) income	**(2,799,606)**	**810,098**	**(3,609,704)**	(446)%
Cumulative dividends on Series A preferred stock	(21,134)	(36,685)	15,551	(42)%
Net (loss) income attributable to common stockholders	**$ (2,820,740)**	**$ 773,413**	**$ (3,594,153)**	(465)%

Revenues

For the quarter ended December 31, 2021, grant revenue was approximately $0.2 million compared to $0.1 million for the year ended December 31, 2020. The increase in revenue of approximately $0.1 million is due to timing of reimbursements received from the FDA as a result of achieving certain clinical milestones in the development of TMB-001. In September 2018, Patagonia was awarded a $1.5 million grant (the “Grant”) from the FDA as part of the Orphan Products Clinical Trials Grants Program of the Office of Orphan Products Development. The Grant funds were made available in three annual installments of $500,000 per year, which commenced in September 2018. The Grant was transferred to Timber pursuant to its TMB-001 Acquisition Agreement with Patagonia in February 2019. In March 2020 and March 2021, the FDA awarded us the second and third tranches of the grant, respectively.

There were no Milestone revenues for the quarters ended December 31, 2021 and 2020, respectively.

Operating Costs and Expenses

Research and Development Expense

For the quarter ended December 31, 2021, research and development expenses were $1.5 million compared to $0.5 million for the quarter ended December 31, 2020. The increase of $1.0 million is primarily related to increased costs incurred related to our Phase 2b and Phase 2a clinical trials of TMB-001 and TMB-002, respectively, such as CRO direct and pass-through expenses.

Research and development costs were primarily attributable to costs incurred in connection with our research activities and include costs associated with clinical trials, consultants, clinical trial materials, regulatory filings, facilities, laboratory expenses and other supplies.

General and Administrative Expense

For the quarter ended December 31, 2021, general and administrative expenses were $1.5 million compared to $1.3 million for the quarter ended December 31, 2020. The increase in general and administrative expenses of approximately $0.2 million was due to increased personnel and related costs including stock-based compensation of $0.2 million due to increased headcount.

Other Income (Expense)

Interest Expense

Interest expense was $0.02 million for the quarter ended December 31, 2021, which was due to interest charged for the Redeemable Series A convertible preferred stock under redemption, which started in November 2021. For the quarter ended December 31, 2020, there was no interest expense.

Change in Fair Value of Warrant Liability

For the quarter ended December 31, 2020, the change in fair value of warrant liability resulted in an unrealized gain of $2.5 million due to the decrease in share price during the period.

Liquidity and Capital Resources

Since inception, we have not generated revenue from product sales and have incurred net losses and negative cash flows from its operations. At December 31, 2021, we had working capital of approximately $12.9 million, which included cash and cash equivalents of $16.8 million. We reported a net loss of $10.6 million, during the year ended December 31, 2021. During the year ended December 31, 2021, we raised net proceeds of $15.8 million from our offering of common stock and prefunded warrants. Our management believes that the Company's existing cash and cash equivalents as of December 31, 2021 are sufficient to satisfy our operating cash needs into the fourth quarter of 2022.

Inflation has not had a significant impact on our historical operations, and we while we do not expect it to have a significant impact on our results of operations or financial condition in the near term, we have monitored and will continue to monitor, the cost of clinical trials and our operating expenses for the potential impact of inflation.

Cash Flows for the Year Ended December 31, 2021 and 2020

	Year Ended December 31,	
	2021	2020
Cash provided by (used in) continuing operations:		
Operating activities	$ (9,314,160)	$ (8,293,313)
Investing activities	(17,804)	(2,659,214)
Financing activities	15,791,810	21,244,147
Net increase in cash and cash equivalents	$ 6,459,846	$ 10,291,620

Operating Activities

For the year ended December 31, 2021, net cash used in operating activities was $9.3 million, which primarily consisted of our net loss of $10.6 million, adjusted for non-cash expenses of $0.9 million primarily consisting of, $0.6 of stock-based compensation and $0.3 million of amortization of the right of use assets. The change in assets and liabilities of $0.4 million is primarily due to increases in accounts payable and accrued expenses of $0.6 million and a reduction in the lease liability of $0.3 million.

For the year ended December 31, 2020 net cash used in operating activities was $8.3 million, which primarily consisted of our net loss of $15.1 million, adjusted for non-cash expenses of $7.7 million primarily consisting of, $12.4 million of research and development – licenses acquired, $4.2 million of amortization of debt discount related to the Bridge Notes, offset by $8.2 million for the change in fair value of our warrant liability, $0.8 million for the amortization of our loan discount, and $0.6 million for the change in fair value of our investment in BioPharmX. The change in assets and liabilities of $0.9 million is primarily due to increases in other current assets and a decrease in accounts payable, accrued expenses and other liabilities of $0.6 million.

Investing Activities

For the year ended December 31, 2020, net cash used in investing activities was approximately $2.7 million which primarily consisted of our loan to BioPharmX of $2.3 million and our payment of $0.8 million for research and development licenses, offset by the cash acquired with our acquisition of BioPharmX of $0.3 million.

Financing Activities

For the year ended December 31, 2021, net cash provided by financing activities was approximately $15.8 million which consisted of the net proceeds received from the issuance of common stock and pre-funded warrants from the November 2021 Offering.

For the year ended December 31, 2020, net cash provided by financing activities was approximately $21.2 million, which consisted of the net proceeds received from the issuance of common stock related to our financing of $17.5 million and the proceeds received from our Bridge Notes of $3.7 million.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of our pipeline of programs. Our expenses related to clinical trials are expected to increase in 2022. Furthermore, we expect to continue to incur costs as a public company. Accordingly, we will need to obtain additional funding. If we are unable to raise capital or otherwise obtain funding when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our research and development expenses in connection with our development programs for our various product candidates will continue to be significant. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future.

On July 17, 2020, we entered into an Amended and Restated Registration Rights Agreement (as amended, the "Registration Rights Agreement") with the Investors. Pursuant to the Registration Rights Agreement, we agreed to provide certain demand registration rights to the Investors relating to the registration of the shares underlying the Investor Warrants and the Bridge Warrants. In connection with the entry into the Registration Rights Agreement and pursuant to the Securities Purchase Agreement, we were restricted from various financing activities until August 16, 2022. On November 19, 2020 we entered into a warrant waiver agreement with the investors revising the restriction date to April 30, 2021, except with respect to variable rate transactions. We remain restricted with respect to conducting variable rate transactions until May 18, 2023.

On July 5, 2019, we entered into a license agreement with AFT which provides us with (i) an exclusive license to certain licensed patents, licensed know-how and AFT trademarks to commercialize the Pascomer® product in the United States, Canada and Mexico and (ii) a co-exclusive license to develop the Pascomer® product in this territory. Concurrently, we granted to AFT an exclusive license to commercialize the Pascomer® product outside of its territory and co-exclusive sublicense to develop and manufacture the licensed product for commercialization outside of its territory (the "AFT License Agreement").

Upon closing of the AFT License Agreement, we were obligated to reimburse AFT for previously spent development costs, subject to certain limitations and were obligated to pay a one-time, irrevocable and non-creditable upfront payment to AFT, payable in scheduled installments. AFT is entitled to up to $25.5 million of cash milestone payments relating to certain regulatory and commercial achievements of TMB-002, with the first payment of $1.0 million upon the successful completion of a Phase 2b trial where the results of such clinical trial meet the clinical trial's primary clinical endpoints. In addition, AFT is entitled to net sales royalties ranging from high single digits to low double digits for the program licensed. The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 or 2020, respectively. Management believes that in 2022 AFT may achieve certain regulatory achievements that would require the Company to make a $1.0 million milestone payment, but certainty of regulatory achievement is not assured.

The Company has a class of Series A Preferred Stock as to which the holder TardiMed has demanded redemption. The redemption price is equal to approximately $2.1 million in the aggregate, at December 31, 2021, including accumulated and unpaid dividends which accrue dividends at the rate of 8% per annum. Redemption is subject to certain limitations under Delaware corporate law due to our current financial condition. As a result of the call for redemption, the Series A Preferred Stock has been reclassified as a liability at December 31, 2021. Dividends will continue to accrue and will be recorded as non-cash interest expense in the Statement of Operations rather than to additional-paid-in-capital in 2022.

In addition, under the terms of the TMB 001 Acquisition, we paid a one-time upfront payment of $50,000 to Patagonia. Patagonia is entitled to up to $27.0 million of cash milestone payments relating to certain regulatory and commercial achievements of the TMB 001 Acquisition, with the first being $4.0 million from the initiation of a Phase 3 pivotal trial, as agreed with the FDA. In addition, Patagonia is entitled to net sales earn-out payments ranging from low single digits to mid-double digits for the program licensed. We are responsible for all development activities under the license. The potential regulatory and commercial milestones were not yet considered probable at December 31, 2021 and December 2020, respectively, and no milestone payments have been accrued at December 31, 2021 or 2020, respectively. Management believes that the first $4.0 million milestone payment will likely become payable during 2022.

We have evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year beyond the filing of this Annual Report on Form 10-K. Based on such evaluation and the Company's current plans, which are subject to change, management believes that the Company's existing cash and cash equivalents as of December 31, 2021 are sufficient to satisfy our operating cash needs into the fourth quarter of 2022.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our ability to raise additional funds to finance our operations;
- the outcome, costs and timing of clinical trial results for our current or future product candidates, including the timing, progress, costs and results of our planned Phase3 clinical trial of TMB-001 for the treatment of congenital ichthyosis as well as its ongoing Phase 2b clinical trial of TMB-002 for the treatment of facial angiofibromas in tuberous sclerosis complex;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the emergence and effect of competing or complementary products;
- our ability to maintain, expand and defend the scope of its intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost and timing of completion of commercial-scale manufacturing activities , if any of our products are approved for commercial sale;;
- the cost of establishing sales, marketing and distribution capabilities for the Company's products in regions where we choose to commercialize our products on our own if approved for commercial sale;
- the initiation, progress, timing and results of the commercialization of our product candidates, if approved for commercial sale;
- our ability to retain our current employees and the need and ability to hire additional management and scientific and medical personnel; and
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish.

We will need to raise substantial additional funds through one or more of the following: issuance of additional debt or equity and/or the completion of a licensing or other commercial transaction for one or more of our product candidates. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. There can be no assurance that we will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or convertible debt financings will likely have a dilutive effect on the holdings of our existing stockholders.

The impact of the worldwide spread of COVID-19 has been unprecedented and unpredictable. Site activation and patient enrollment have recently been impacted by the COVID-19 pandemic in the larger and longer TMB-002 study, especially at our contracted test sites in Western Europe. We are continuing to assess the effect on our operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world and our assessment of the impact of COVID-19 may change.

Critical Accounting Policies and Significant Estimates

Research and Development

Research and development costs, including in-process research and development acquired as part of an asset acquisition for which there is no alternative future use, are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Certain research and development costs are estimated based on contractual arrangements.

Accrued Outsourcing Costs

Substantial portions of the Company's preclinical studies and clinical trials are performed by third-party laboratories, medical centers, contract research organizations and other vendors (collectively "CROs"). These CROs generally bill monthly or quarterly for services performed, or bill based upon milestone achievement. For preclinical studies, the Company accrues expenses based upon estimated percentage of work completed and the contract milestones remaining. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as CROs, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the number of patients in the trial, the attrition rate at which patients leave the trial, and/or the period over which clinical investigators or CROs are expected to provide services. The Company's estimates depend on the timeliness and accuracy of the data provided by the CROs regarding the status of each program and total program spending. The Company periodically evaluates the estimates to determine if adjustments are necessary or appropriate based on information it receives.

Valuation of Warrant Liabilities

The Company accounts for certain common stock warrants outstanding as a liability at fair value and adjusts the instruments to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's statements of operations. The Company issued Series A Warrants to purchase 8,384,764 shares of its common stock to investors in connection with the $20 million financing in May 2020, and recorded these outstanding warrants as a liability at fair value utilizing a Monte Carlo simulation model. As further described in Note 6, the fair value of the warrants issued by the Company in connection with the $5.0 million Bridge Notes has been estimated using a probability-weighted Black-Scholes option pricing model. Upon consummation of the Merger the Series B Warrants were classified as equity.

Pursuant to the waiver agreement related to the Company's Series A Warrants (see Note 1), on November 19, 2020, the warrant liability was reclassified to additional paid-in capital.

Stock-Based Compensation

The Company expenses stock-based compensation to employees, non-employees and board members over the requisite service period based on the estimated grant-date fair value of the awards and actual forfeitures. The Company accounts for forfeitures as they occur. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's role at the Company.

The Company estimates the fair value of VARs using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of equity-based awards represented management's best estimates and involve inherent uncertainties and the application of management's judgment. All equity-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations.

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to our financial statements beginning on page F-1 of this Form 10-K for a description of recent accounting pronouncements applicable to our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated audited financial statements as of and for the years ended December 31, 2021 and December 31, 2020, together with the report of the independent registered public accounting firm thereon and the notes thereto, are presented beginning at page F-2.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As required by Rule 13a-15 under the Exchange Act, we have carried out an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this annual report, December 31, 2021. This evaluation was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our Company's reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2021.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with GAAP. Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on its financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021 based on criteria established in the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm because as a smaller reporting company we are not subject to Section 404(b) of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control over Financial Reporting

During the fourth quarter of the year ended December 31, 2021 there have been no changes that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is hereby incorporated by reference from the information appearing under the captions "Proposal No. 1: Election of Directors" and "Corporate Governance" in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2021. Notwithstanding the foregoing, in accordance with the instructions to Item 407(e)(5) of Regulation S-K, the information contained in our proxy statement under the sub-heading "Compensation Committee Report" shall not be deemed to be filed as part of or incorporated by reference into this annual report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is hereby incorporated by reference from the information appearing under the captions “Corporate Governance” and “Executive and Director Compensation” in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2021. Notwithstanding the foregoing, in accordance with the instructions to Item 407(e)(5) of Regulation S-K, the information contained in our proxy statement under the sub-heading “Compensation Committee Report” shall not be deemed to be filed as part of or incorporated by reference into this annual report on Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is hereby incorporated by reference from the information appearing under the captions “Stock Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2021.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is hereby incorporated by reference from the information appearing under the captions “Corporate Governance” and “Transactions with Related Persons” in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2021.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our independent registered public accounting firm is KPMG LLP, Short Hills, NJ, Auditor ID: 185.

The information required by this Item as to the fees we pay our principal accountant is hereby incorporated by reference from the information appearing under the caption “Ratification and Approval of Independent Auditors” in our definitive proxy statement which involves the election of directors and is to be filed with the Commission pursuant to the Securities Exchange Act of 1934 within 120 days of the end of our fiscal year on December 31, 2021.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

1. Financial Statements

The list of consolidated financial statements set forth in the accompanying Index to the Consolidated Financial Statements at page F-1 of this Annual Report on Form 10-K is incorporated herein by reference. Such consolidated financial statements are filed as part of this Annual Report on Form 10-K.

2. Financial Statement Schedules

All schedules have been omitted because the required information is either not required, not applicable or because the information required is included in the consolidated financial statements or notes thereto.

3. Exhibits

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated January 28, 2020 among Timber Pharmaceuticals, Inc. (f/k/a BioPharmX Corporation), BITI Merger Sub, Inc., and Timber Pharmaceuticals LLC (incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on January 29, 2020).**
2.2	Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated March 24, 2020, among Timber Pharmaceuticals, Inc. (f/k/a BioPharmX Corporation), BITI Merger Sub, Inc. and Timber Pharmaceuticals LLC (incorporated by reference to Exhibit 2.3 to the Company's Amendment No. 1 to the Registration Statement on Form S-4/A filed with the SEC on March 30, 2020).
2.3	Amendment No. 2 to Agreement and Plan of Merger and Reorganization, dated April 27, 2020, among Timber Pharmaceuticals, Inc. (f/k/a BioPharmX Corporation), BITI Merger Sub, Inc. and Timber Pharmaceuticals LLC (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on April 27, 2020).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 4.01 to our Registration Statement on Form S-8 (File No. 333-201708), filed with the SEC on January 26, 2015).
3.2	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.5 to our Annual Report on Form 10-K (File No. 001-37411), filed with the SEC on April 21, 2017).
3.3	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on April 26, 2019).
3.4	Certificate of Amendment to Certificate of Incorporation (incorporated by reference to the Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on May 22, 2020).
3.5	Certificate of Amendment to Certificate of Incorporation, (incorporated by reference to the Exhibit 3.2 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on May 22, 2020).
3.6	Amended and Restated Bylaws of BioPharmX Corporation (incorporated by reference to Exhibit 3.2 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on April 26, 2019).
3.7	Certificate of Elimination of Certificate of Designations, Preferences and Rights of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on March 18, 2016).
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to our Registration Statement on Form S-1/A (File No. 333-214116), filed with the SEC on November 18, 2016).
3.9	Certificate of Elimination of Certificate of Designation of Preferences and Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on March 9, 2018).
3.10	Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.8 to our Registration Statement on Form S-4/A (File No. 333-236526), filed with the SEC on March 30, 2020).

4.1	Specimen Stock Certificate (incorporated by reference to Exhibit 4.7 to our Registration Statement on Form S-8 (File No. 333-239216), filed with the SEC on June 16, 2020).
4.2	Amended and Restated Registration Rights Agreement, dated July 17, 2020, by and between Timber Pharmaceuticals, Inc. (f/k/a BioPharmX Corporation) and the investors named therein (incorporated by reference to Exhibit 4.1 to our Quarterly Report on Form 10-Q (File No. 001-37411), filed with the SEC on August 18, 2020).
4.3	Form of Series A Warrants to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on June 3, 2020).
4.4	Form of Bridge Warrants to Purchase Common Stock (incorporated by reference to Exhibit 4.20 to our Registration Statement on Form S-4/A (File No. 333-236526), filed with the SEC on March 30, 2020).
4.5	Description of Capital Stock (incorporated by reference to Exhibit 4.6 to our Annual Report on Form 10-K (File No. 001-37411), filed with the SEC on March 28, 2021).
4.6	Form of Warrant (incorporated by reference to Exhibit 4.2 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on November 4, 2021.
10.1	Lease Agreement entered into on October 30, 2018 between Timber Pharmaceuticals, Inc. (f/k/a BioPharmX, Inc.) and The Irvine Company LLC (incorporated by reference to Exhibit 10.1 to our Current Report (File No. 000-37411), filed with the SEC on October 31, 2018)#.
10.2	Form of 2014 Equity Incentive Plan award agreement (incorporated by reference to Exhibit 4.05 to our Registration Statement on Form S-8 (File No. 333-201708), filed with the SEC on January 27,2014).#
10.3	2016 Equity Incentive Plan (as amended) (incorporated by reference to Exhibit 99.1 to our Registration Statement on Form S-8 (File No. 333-227262), filed with the SEC on September 10, 2018).#
10.4	Form of Stock Option Agreement (incorporated by reference to Exhibit 4.05 to our Registration Statement on Form S-8 (File No. 333-213627), filed with the SEC on September 14, 2016).#
10.5	Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 4.06 to our Registration Statement on Form S-8 (File No. 333-213627), filed with the SEC on September 14, 2016).#
10.6	Form of Stock Bonus Award Agreement (incorporated by reference to Exhibit 4.07 to our Registration Statement on Form S-8 (File No. 333-213627), filed with the SEC on September 14, 2016).#
10.7	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 4.08 to our Registration Statement on Form S-8 (File No. 333-213627), filed with the SEC on September 14, 2016).#
10.8	Form of Stock Appreciation Right Award Agreement (incorporated by reference to Exhibit 4.09 to our Registration Statement on Form S-8 (File No. 333-213627), filed with the SEC on September 14, 2016).#
10.9	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.16 to our Registration Statement on Form S-1 (File No. 333-203317), filed with the SEC on May 14, 2015).
10.10	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on September 27, 2016).

10.11	Bridge Loan Credit Agreement, dated January 28, 2020, between Timber Pharmaceuticals, Inc. (f/k/a BioPharmX Corporation) and Timber Pharmaceuticals LLC (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on January 29, 2020).
10.12	Note, dated January 28, 2020, made by Timber Pharmaceuticals, Inc. (f/k/a BioPharmX Corporation) in favor of Timber Pharmaceuticals LLC (incorporated by reference to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on January 29, 2020).
10.13	Form of Exchange Agreement, dated January 28, 2020, between Timber Pharmaceuticals, Inc. (f/k/a BioPharmX Corporation) and certain investors (incorporated by reference to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on January 29, 2020).
10.14	Sublease Agreement, dated as of February 14, 2020, by and between Timber Pharmaceuticals, Inc. (f/k/a BioPharmX Corporation) and Full Cycle Bioplastics, Inc. (incorporated by reference to our Current Report on Form 8-K (File No. 001-37411), filed on February 18, 2020).
10.15	Securities Purchase Agreement, dated March 27, 2020, by and among Timber, BioPharmX, and certain investors party thereto (incorporated by reference to Exhibit 10.33 of our Registration Statement on Form S-4/A (File No. 333-236526), filed with the SEC on March 30, 2020.
10.16	Offer Letter, dated June 20, 2019, by and between John Koconis and Timber Pharmaceuticals LLC (incorporated by reference to Exhibit 10.28 of our Registration Statement on Form S-4 (File No. 333-256526), filed with the SEC on February 20, 2020).#
10.17	Offer Letter, dated March 31, 2020, by and between Joseph Lucchese and Timber Pharmaceuticals LLC (incorporated by reference to Exhibit 10.5 of our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on May 22, 2020).#
10.18	Asset Acquisition Agreement, dated February 28, 2019, by and among Timber Pharmaceuticals LLC, Patagonia Pharmaceuticals LLC, Johnathan Rome and Zachary Rome (incorporated by reference to Exhibit 10.27 of our Registration Statement on Form S-4 (File No. 333-236526), filed with the SEC on February 20, 2020).
10.19	Asset Acquisition Agreement, dated June 26, 2019, by and among Timber Pharmaceuticals LLC, Patagonia Pharmaceuticals LLC, Jonathan Rome and Zachary Rome (incorporated by reference to Exhibit 10.29 of our Registration Statement on Form S-4 (File No. 333-236526), filed with the SEC on February 20, 2020).**
10.20	License Agreement, dated July 5, 2019, by and between AFT Pharmaceuticals Limited and Timber Pharmaceuticals LLC (incorporated by reference to Exhibit 10.30 of our Registration Statement on Form S-4 (File No. 333-236526), filed with the SEC on February 20, 2020).***
10.21	Timber Pharmaceuticals, Inc. 2020 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 10.25 to our Annual Report on Form 10-K (File No. 001-37411), filed with the SEC on March 23, 2021).#
10.22	Amendment to the Timber Pharmaceuticals, Inc. 2020 Omnibus Equity Incentive Plan, dated April 20, 2021 (incorporated by reference to Exhibit 4.9 to our Registration on Form S-8 (File No. 333-259830) filed with the SEC on September 27, 2021).#
10.23	Form of Incentive Stock Option Grant Agreement (incorporated by reference to Exhibit 10.26 to our Annual Report on Form 10-K (File No. 001-37411), filed with the SEC on March 23, 2021).#
10.24	Form of Nonqualified Stock Option Grant Agreement (incorporated by reference to Exhibit 10.27 to our Annual Report on Form 10-K (File No. 001-37411), filed with the SEC on March 23, 2021).#

10.25	Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.28 to our Annual Report on Form 10-K (File No. 001-37411), filed with the SEC on March 23, 2021).#
10.26	Form of Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.29 to our Annual Report on Form 10-K (File No. 001-37411), filed with the SEC on March 23, 2021).#
10.27	Form of Amendment No. 1 to Securities Purchase Agreement, dated April 27, 2020, by and among Timber, BioPharmX and certain investors parties thereto (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on April 27, 2020).
10.28	Offer Letter, dated January 19, 2021, between Alan Mendelsohn, M.D. and Timber Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on January 25, 2021).
10.29	Form of Waiver Agreement (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on November 20, 2020).
10.30	Lease Agreement, dated March 10, 2021, by and between Timber Pharmaceuticals, Inc. and SIG 110 LLC (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-37411), filed with the SEC on March 16, 2021).
21.1	Subsidiaries of the Registrant.*
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.*
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.*
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.*
32.1	Certification of Chief Executive Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.*
32.2	Certification of Chief Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.*
101.INS	Inline XBRL Instance Document.*
101.SCH	Inline XBRL Taxonomy Schema Linkbase Document.*
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.*
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.*
101.LAB	Inline XBRL Taxonomy Labels Linkbase Document.*
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101).*

* Filed herewith.

**	All schedules and exhibits to the agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.
***	Certain identified information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.
#	Management compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized in Basking Ridge, New Jersey on March 31, 2022.

TIMBER PHARMACEUTICALS, INC.

By: /s/ John Koconis
John Koconis
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Joseph Lucchese
Joseph Lucchese
Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ John Koconis John Koconis	Chief Executive Officer (Principal Executive Officer and Chairman of the Board)	March 31, 2022
/s/ Joseph Lucchese Joseph Lucchese	Chief Financial Officer (Principal Financial Officer and Accounting Officer	March 31, 2022
/s/ Zachary Rome Zachary Rome	Director	March 31, 2022
/s/ Edward J Sitar Edward J Sitar	Director	March 31, 2022
/s/ Gianluca Pirozzi Gianluca Pirozzi	Director	March 31, 2022
/s/ David Cohen David Cohen	Director	March 31, 2022
/s/ Lubor Gaal Lubor Gaal	Director	March 31, 2022

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Timber Pharmaceuticals, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Timber Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, members' and stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

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

/s/ KPMG LLP

We have served as the Company's auditor since 2019.

Short Hills, New Jersey
March 31, 2022

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash	$ 16,808,539	$ 10,348,693
Other current assets	310,238	377,290
Total current assets	17,118,777	10,725,983
Deposits	127,534	114,534
Property and equipment, net	16,377	—
Right of use asset	638,786	787,432
Total assets	**$ 17,901,474**	**$ 11,627,949**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 953,349	$ 395,049
Accrued expenses	850,557	768,661
Lease liability, current portion	332,817	217,651
Redeemable Series A convertible preferred stock under redemption **(Note 9)**	2,055,348	—
Total current liabilities	4,192,071	1,381,361
Notes payable	37,772	37,772
Lease liability	331,152	579,455
Deferred tax liability	—	37,842
Other liabilities	73,683	73,683
Total liabilities	**4,634,678**	**2,110,113**
Commitments and contingencies (Note 8)		
Redeemable Series A convertible preferred stock, par value $0.001; 2,500 shares authorized; 1,819 shares issued and outstanding as of December 31, 2020	—	1,909,805
Stockholders' equity		
Common stock, par value $0.001; 450,000,000 shares authorized; 63,619,140 shares issued and outstanding as of December 31, 2021, and 27,132,420 shares issued and outstanding as of December 31, 2020	63,619	27,132
Additional paid-in capital	42,087,719	25,826,295
Accumulated deficit	(28,884,542)	(18,245,396)
Total stockholders' equity	13,266,796	7,608,031
Total liabilities, redeemable convertible preferred stock, and stockholders' equity	**$ 17,901,474**	**$ 11,627,949**

The accompanying notes are an integral part of these consolidated financial statements.

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
Consolidated Statements of Operations

	Year ended December 31,	
	2021	**2020**
Grant revenue	$ 590,794	$ 453,810
Milestone revenue	295,738	—
Total revenue	886,532	453,810
Operating costs and expenses		
Research and development	6,149,586	2,733,026
Research and development - license acquired	—	12,371,332
Transaction costs	—	1,501,133
Selling, general and administrative	5,387,164	4,060,186
Total operating expenses	11,536,750	20,665,677
Loss from operations	(10,650,218)	(20,211,867)
Other (expense) income		
Interest expense	(15,551)	(4,416,746)
Interest income	—	816,657
Change in fair value of investment in BioPharmX	—	559,805
Change in fair value of warrant liability	—	8,156,770
(Loss) gain on foreign currency exchange	(3,619)	15,609
Total other (expense) income	(19,170)	5,132,095
Loss before provision for income taxes	**(10,669,388)**	**(15,079,772)**
(Benefit) Provision for income taxes	(30,242)	37,842
Net loss	**(10,639,146)**	**(15,117,614)**
Accrued dividend on preferred stock units	—	(52,669)
Cumulative dividends on Series A preferred stock	(129,992)	(90,516)
Net loss attributable to common stockholders	**$ (10,769,138)**	**$ (15,260,799)**
Basic and diluted net loss per share attributable to common stockholders	$ (0.27)	$ (0.97)
Basic and diluted weighted average number of shares outstanding	40,440,570	15,699,869

The accompanying notes are an integral part of these consolidated financial statements.

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
Consolidated Statements of Members' and Stockholders' Equity

	Series A Preferred Stock		Preferred Units		Common Units		Common Stock		Additional	Accumulated	Total
	Shares	Amount	Units	Amount	Units	Amount	Shares	Amount	Paid-in Capital	Deficit	Stockholder's Equity
Balance at January 1, 2020	**—**	**$ —**	**1,624,228**	**$ 1,624,228**	**10,000**	**$ 74,667**	**—**	**$ —**	**$ —**	**$ (3,075,113)**	**$ (1,376,218)**
Issuance of common stock for acquisition of BioPharmX	—	—	—	—	—	—	1,367,326	1,367	8,366,666	—	8,368,033
Issuance of common stock and warrants, net of issuance costs	—	—	—	—	—	—	4,185,981	4,186	17,495,814	—	17,500,000
Series A liability classified warrants	—	—	—	—	—	—	—	—	(16,511,634)	—	(16,511,634)
Bridge loan converted to equity	—	—	—	—	—	—	—	—	5,000,000	—	5,000,000
Reclassification of bridge warrant	—	—	—	—	—	—	—	—	3,423,204	—	3,423,204
Non-cash contribution from TardiMed	—	—	142,392	142,392	—	—	—	—	—	—	142,392
Accrued preferred unit dividend	—	—	52,669	52,669	—	—	—	—	—	(52,669)	—
Conversion of common units to common stock pursuant to BioPharmX acquisition	—	—	—	—	(10,000)	(74,667)	6,295,724	6,296	68,371	—	—
Conversion of preferred units to Series A preferred stock pursuant to BioPharmX acquisition	1,819	1,819,289	(1,819,289)	(1,819,289)	—	—	—	—	—	—	(1,819,289)
Accrued dividend Series A preferred stock	—	90,516	—	—	—	—	—	—	(90,516)	—	(90,516)
Exercise of Series B warrants	—	—	—	—	—	—	15,283,389	15,283	(8,906)	—	6,377
Reclassification of Series A warrant liability	—	—	—	—	—	—	—	—	7,864,377	—	7,864,377
Stock-based compensation	—	—	—	—	—	—	—	—	218,919	—	218,919
Net loss	—	—	—	—	—	—	—	—	—	(15,117,614)	(15,117,614)
Balance at December 31, 2020	**1,819**	**$ 1,909,805**	**—**	**$ —**	**—**	**$ —**	**27,132,420**	**$27,132**	**$ 25,826,295**	**$ (18,245,396)**	**$ 7,608,031**
Accrued dividend Series A preferred stock	—	129,992	—	—	—	—			(129,992)	—	(129,992)
Exercise of Series A warrants	—	—	—	—	—	—	2,059,613	2,060	(2,060)	—	—
Exercise of Series B warrants	—	—	—	—	—	—	7,467,652	7,468	(7,468)	—	—
Issuance of common stock and warrants, net of issuance costs	—	—	—	—	—	—	26,953,125	26,953	15,764,857	—	15,791,810
Exercise of VARs	—	—	—	—	—	—	6,330	6	(6)	—	—
Reclassification of Series A preferred stock	—	(2,039,797)	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	636,093	—	636,093
Net loss	—	—	—	—	—	—	—	—	—	(10,639,146)	(10,639,146)
Balance at December 31, 2021	**1,819**	**$ —**	**—**	**$ —**	**—**	**$ —**	**63,619,140**	**$63,619**	**$ 42,087,719**	**$ (28,884,542)**	**$ 13,266,796**

The accompanying notes are an integral part of these consolidated financial statements.

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
Consolidated Statements of Cash Flows

	Year ended December 31, 2021	2020
Cash flows from operating activities		
Net loss	$ (10,639,146)	$ (15,117,614)
Adjustments to reconcile net loss to net cash used in operating activities:		
Research and development-licenses acquired	—	12,371,332
Non-cash contribution from TardiMed	—	142,392
Stock-based compensation	636,093	218,919
Change in fair value of warrant liability	—	(8,156,770)
Change in fair value of investment in BioPharmX	—	(559,805)
Amortization of loan discount	—	(775,000)
Amortization of debt discount	—	4,232,718
Amortization of right of use assets	271,455	116,938
Depreciation	1,427	—
Deferred taxes	(37,842)	37,842
Non-cash Interest on Redeemable Preferred Stock	15,551	—
Accrued interest on BioPharmX loan	—	(41,655)
Accrued interest on bridge notes	—	183,333
Changes in assets and liabilities:		
Other current assets	67,052	(342,443)
Deposits	(13,000)	—
Accounts payable	558,300	(716,525)
Accrued expenses	81,896	221,671
Lease liability	(255,946)	(108,646)
Net cash used in operating activities	(9,314,160)	(8,293,313)
Cash flows from investing activities		
Cash acquired with acquisition of BioPharmX	—	340,786
Loan to BioPharmX	—	(2,250,000)
Purchase of property and equipment	(17,804)	—
Purchase of research and development licenses - AFT Pharmaceuticals Limited	—	(750,000)
Net cash used in investing activities	(17,804)	(2,659,214)
Cash flows from financing activities		
Proceeds from PPP loan	—	37,772
Proceeds from the issuance of common stock and warrants, net of issuance costs	15,791,810	17,500,000
Proceeds from bridge notes payable	—	3,700,000
Proceeds from the exercise of Series B warrants		6,375
Net cash provided by financing activities	15,791,810	21,244,147
Net increase in cash	6,459,846	10,291,620
Cash, beginning of period	10,348,693	57,073
Cash, end of period	$ 16,808,539	$ 10,348,693
Non-cash investing and financing activities:		
Issuance of common stock for acquisition of BioPharmX	$ —	$ 8,368,032
Conversion of preferred units to Series A preferred stock pursuant to BioPharmX acquisition	$ —	$ 1,819,289
Conversion of common units to common stock pursuant to BioPharmX acquisition	$ —	$ 74,667
Bridge loan converted to equity	$ —	$ 5,000,000
Reclassification of bridge warrant	$ —	$ 3,423,204
Series A liability classified warrants	$ —	$ 16,511,634
Reclassification of Series A warrant liability		$ 7,864,377
Accrued Series A preferred stock dividend	$ 129,992	$ —
Cashless exercise of Series A warrants	$ 2,060	$ —
Cashless exercise of Series B warrants	$ 7,468	$ —
Cashless exercise of VARs	$ 6	$ —

The accompanying notes are an integral part of these consolidated financial statements

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
Notes to Consolidated Financial Statements

Note 1. Organization and description of business operations

Timber Pharmaceuticals, Inc., formerly known as BioPharmX Corporation (together with its subsidiary Timber Pharmaceuticals Australia Pty Ltd. and Timber Pharmaceuticals LLC, the "Company" or "Timber") is incorporated under the laws of the state of Delaware. Timber was founded in 2019 to develop treatments for unmet needs in medical dermatology. Timber has a particular focus on rare diseases or conditions of the skin for which there are no current treatments. Timber is initially targeting multiple indications in rare/orphan dermatology with no approved treatments.

Merger Agreement

On May 18, 2020, BioPharmX Corporation ("BioPharmX") completed its business combination with Timber Pharmaceuticals LLC, a Delaware limited liability company ("Timber Sub"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of January 28, 2020 (the "Merger Agreement"), by and among BioPharmX, Timber Sub and BITI Merger, Inc., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"), as amended by Amendment No. 1 thereto made and entered into as of March 24, 2020 (the "First Amendment") and Amendment No. 2 thereto made and entered into as of April 27, 2020 (the "Second Amendment") (the Merger Agreement, as amended by the First Amendment and the Second Amendment, the "Amended Merger Agreement"), pursuant to which Merger Sub merged with and into Timber Sub, with Timber Sub surviving as a wholly-owned subsidiary of the Company (the "Merger"). In connection with, and immediately prior to the completion of, the Merger, BioPharmX effected a reverse stock split of the Company's common stock, par value $0.001 per share (the "Common Stock"), at a ratio of 1-for-12 (the "Reverse Stock Split"). Immediately after completion of the Merger, BioPharmX changed its name to "Timber Pharmaceuticals, Inc." and the officers and directors of Timber Sub became the officers and directors of the Company.

Under the terms of the Amended Merger Agreement, BioPharmX issued shares of Common Stock to the holders of common units of Timber Sub. Immediately after the Merger, there were approximately 11,849,031 shares of Common Stock outstanding (after the Reverse Stock Split). Pursuant to the terms of the Amended Merger Agreement, the former holders of common units of Timber Sub (including the Investors, as defined below, but excluding Value Appreciation Rights of Timber Sub ("VARs"), owned in the aggregate approximately 88.5% of the outstanding Common Stock, with the Company's stockholders immediately prior to the Merger owning approximately 11.5% of the outstanding Common Stock. The number of shares of Common Stock issued to the holders of common units of Timber Sub for each common unit of Timber Sub outstanding immediately prior to the Merger was calculated using an exchange ratio of approximately 629.57 shares of Common Stock for each Timber Sub unit. In addition, the 584 VARs that were outstanding immediately prior to Merger became denoted and payable in 367,670 shares of Common Stock at the Effective Time of the Merger (the "Effective Time"). Further, the holder of the 1,819,289 preferred units of Timber Sub outstanding immediately prior to the Merger received 1,819 shares of the newly created convertible Series A preferred stock at the Effective Time. As part of the Merger, the Company assumed 220,030 legacy BioPharmX warrants with a weighted average exercise price of $164.17 per share, and 97,870 legacy BioPharmX stock options with a weighted average exercise price of $45.81 per share. In connection with the Merger Agreement, BioPharmX entered into a Credit Agreement with Timber Sub, pursuant to which Timber Sub made a bridge loan to the Company (the "Bridge Loan"), in an aggregate amount of $2.25 million with $250,000 original issue discount.

The Company incurred approximately $1.5 million of legal, consulting, and other professional fees related to the Merger, which were classified as transaction expenses in the accompanying consolidated statement of operations for the year ended December 31, 2020.

Securities Purchase Agreement

On May 18, 2020, Timber and Timber Sub completed a private placement transaction (the "Pre-Merger Financing") with the Investors pursuant to the Securities Purchase Agreement for an aggregate purchase price of approximately $25.0 million (comprised of (i) approximately $5 million credit with respect to the senior secured notes issued in connection with the bridge loan that certain of the Investors made to Timber Sub at the time of the execution of the Merger Agreement and (ii) approximately $20 million in cash from the Investors).

Pursuant to the Pre-Merger Financing, (i) Timber Sub issued and sold to the Investors common units of Timber Sub which converted pursuant to the exchange ratio in the Merger into an aggregate of approximately 4,137,509 shares (the "Converted Shares") of Common Stock; and (ii) the Company agreed to issue to each Investor, on the tenth trading day following the consummation of the Merger, (A) Series A Warrants representing the right to acquire shares of Common Stock ("Series A Warrants") equal to 75% of the sum of (a) the number of Converted Shares issued to the Investor, without giving effect to any limitation on delivery contained in the Securities Purchase Agreement, and (b) the number of shares of Common Stock underlying the Series B Warrants issued to the Investor (the "Series B Warrants") and (B) the Series B Warrants. On June 2, 2020, pursuant to the terms of the Securities Purchase Agreement, the Company issued 8,384,764 Series A Warrants to purchase shares of Common Stock ("Series A Warrants") and 7,042,175 Series B Warrants to purchase shares of Common Stock ("Series B Warrants").

In addition, pursuant to the terms of the Securities Purchase Agreement, dated as of January 28, 2020 between Timber Sub and several of the Investors, the Company issued to such purchasers, on May 22, 2020, warrants to purchase 413,751 shares of Common Stock (the "Bridge Warrants") which originally had an exercise price of $2.2362 per share. As a result of the November 2021 Offering, the exercise price of the Bridge Warrants was adjusted to $0.31 per share

Investor Warrants

Series A Warrants

The Series A Warrants have an exercise price of $1.16 per share, were exercisable upon issuance and will expire on the day following the later to occur of (i) June 2, 2025 and (ii) the date on which the Series A Warrants have been exercised in full (without giving effect to any limitation on exercise contained therein) and no shares remain issuable thereunder. As of December 31, 2021, the Series A Warrants are exercisable for 16,701,824 shares of Common Stock in the aggregate.

Pursuant to the Series A Warrants, the Company has agreed not to enter into, allow or be party to certain fundamental transactions, generally including any merger with or into another entity, sale of all or substantially all of the Company's assets, tender offer or exchange offer, or reclassification of the Common Stock (a "Fundamental Transaction") until May 1, 2021. Thereafter, upon any exercise of a Series A Warrant, the holder shall have the right to receive, for each share of Common Stock that would have been issuable upon such exercise immediately prior to the occurrence of a Fundamental Transaction, at the option of the holder (without regard to any limitation on the exercise of the Series A Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which the Series A Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation on the exercise of the Series A Warrant). For purposes of any such exercise, the determination of the exercise price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the exercise price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of the Series A Warrant following such Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under the Series A Warrants, upon which the Series A Warrants shall become exercisable for shares of Common Stock, shares of the Common Stock of the Successor Entity or the consideration that would have been issuable to the holders had they exercised the Series A Warrants prior to such Fundamental Transaction, at the holders' election. Additionally, at the request of a holder delivered before the 90th day after the consummation of a Fundamental Transaction, the Company must purchase such holder's warrant for the value calculated using the Black-Scholes option pricing model as of the day immediately following the public announcement of the applicable Fundamental Transaction, or, if the Fundamental Transaction is not publicly announced, the date the Fundamental Transaction is consummated.

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
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If the Company fails to issue to a holder of Series A Warrants the number of shares of Common Stock to which such holder is entitled upon such holder's exercise of the Series A Warrants, then the Company shall be obligated to pay the holder on each day while such failure is continuing an amount equal to 1.5% of the market value of the undelivered shares determined using a trading price of Common Stock selected by the holder while the failure is continuing and if the holder purchases shares of Common Stock in connection with such failure ("Series A Buy-In Shares"), then the Company must, at the holder's discretion, reimburse the holder for the cost of such Series A Buy-In Shares or deliver the owed shares and reimburse the holder for the difference between the price such holder paid for the Series A Buy-In Shares and the market price of such shares, measured at any time of the holder's choosing while the delivery failure was continuing.

Further, the Series A Warrants provide that, in the event that the Company does not have sufficient authorized shares to deliver in satisfaction of an exercise of a Series A Warrant, then unless the holder elects to void such attempted exercise, the holder may require the Company to pay an amount equal to the product of (i) the number of shares that the Company is unable to deliver and (ii) the highest volume-weighted average price of a share of Common Stock as quoted on the NYSE American during the period beginning on the date of such attempted exercise and ending on the date that the Company makes the applicable payment.

On November 19, 2020 the Company entered into waiver agreements with each of the holders of the Company's Series A Warrants. Pursuant to the waiver agreements the holders agreed to waive certain provisions in the Warrants in order to allow for one immediate and final reset of the number of shares of common stock underlying the Warrants and the exercise price of the Series A Warrants, and permanently waive the provisions providing for future resets of the number of shares of common stock underlying the Warrants and the exercise price of the Series A Warrants (other than the anti-dilution protection provisions in the Series A Warrants providing for adjustments to the exercise price of the Series A Warrants upon a dilutive issuance). As a result, the exercise price of the Series A Warrants was set at $1.16 per share and the number of shares underlying all of the Series A Warrants was set at 20,178,214.

Series B Warrants

The Series B Warrants had an exercise price of $0.001 per share, were exercisable upon issuance and were exercised in full on March 4, 2021. The Series B Warrants were exercisable for 22,766,776 shares of Common Stock in the aggregate.

On November 19, 2020 the Company entered into waiver agreements with each of the holders of the Company's Series B Warrants. Pursuant to the waiver agreements the holders agreed to waive certain provisions in the Warrants in order to allow for one immediate and final reset of the number of shares of common stock underlying the Series B Warrants. As a result, the number of shares underlying all of the Series B Warrants was set at 22,766,776 and the exercise price remains at $0.001 per share. During the year ended December 31, 2020, 15,292,744 Series B warrants were exercised for 15,284,992 shares of the Company's common stock.

The number of shares underlying a holder's Series B Warrants was calculated using the existing formula set forth in the Series B Warrants and was reached by dividing the initial purchase price paid by the holder under the Purchase Agreement by a "Reset Price", equal to the arithmetic average of the five (5) lowest Weighted Average Prices (as defined in the Warrants) of the Common Stock during the applicable "Reset Period," in this case being the nine Trading Day (as defined in the Warrants) period ending on the Effective Date (but not less than the Reset Floor Price), and subtracting from such quotient the number of shares of Common Stock issued (or that were issuable) under the Purchase Agreement to the holder.

Bridge Warrants

The Bridge Warrants were issued on May 22, 2020, to the Bridge Investors, had an exercise price of $2.2362 per share, were immediately exercisable upon issuance and have a term of five years from the date of issuance. The Bridge Warrants are exercisable for 413,751 shares of Common Stock in the aggregate. As a result of the November 2021 Offering, the exercise price of the Bridge Warrants was adjusted to $0.31 per share.

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The Bridge Warrants provide that if Timber issues or sells or in accordance with the terms of the Bridge Warrants, is deemed to have issued or sold any shares of Common Stock for a price per share lower than the exercise price then in effect subject to certain limited exceptions, then the exercise price of the Bridge Warrants shall be reduced to such lower price per share.

Upon the consummation of a Fundamental Transaction by the Company, upon any exercise of a Bridge Warrant, the holder shall have the right to receive, for each share of Common Stock that would have been issuable upon such exercise immediately prior to the occurrence of a Fundamental Transaction, at the option of the holder (without regard to any limitation on the exercise of the Bridge Warrant), the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which the Bridge Warrant is exercisable immediately prior to such Fundamental Transaction (without regard to any limitation on the exercise of the Bridge Warrant). For purposes of any such exercise, the determination of the exercise price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Company shall apportion the exercise price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of the Bridge Warrant following such Fundamental Transaction. The Company shall cause any Successor Entity to assume in writing all of the obligations of the Company under the Bridge Warrants, upon which the Bridge Warrants shall become exercisable for shares of Common Stock, shares of the Common Stock of the Successor Entity or the consideration that would have been issuable to the holders had they exercised the Bridge Warrants prior to such Fundamental Transaction, at the holders' election.

Additionally, at the request of a holder of a Bridge Warrant delivered before the 90th day after the consummation of a Fundamental Transaction, Timber or the successor entity must purchase such holder's warrant for the value calculated using the Black-Scholes option pricing model as of the day immediately following the public announcement of the applicable Fundamental Transaction, or, if the Fundamental Transaction is not publicly announced, the date the Fundamental Transaction is consummated.

The Bridge Warrants also contain a "cashless exercise" feature that allows the holders to exercise the Bridge Warrants without making a cash payment in the event that there is no effective registration statement registering the shares issuable upon exercise of the Bridge Warrants. The Bridge Warrants are subject to a blocker provision which restricts the exercise of the Bridge Warrants if, as a result of such exercise, the holder, together with its affiliates and any other person whose beneficial ownership of Common Stock would be aggregated with the holder's for purposes of Section 13(d) of the Exchange Act would beneficially own in excess of 4.99% or 9.99% of the outstanding shares of Common Stock (including the shares of Common Stock issuable upon such exercise), as such percentage ownership is determined in accordance with the terms of the Bridge Warrants.

November 2021 Offering

On November 2, 2021, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC, as representative of the several underwriters named in Schedule I thereto, relating to the public offering, issuance and sale of 21,325,000 shares of our common stock and, to certain investors, pre-funded warrants to purchase 2,112,500 shares of common stock, and accompanying warrants to purchase up to an aggregate of 23,437,500 shares of our common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a warrant to purchase one share of common stock. All of the securities sold in the offering were sold by the Company. The public offering price of each share of common stock and accompanying common warrant was $0.64 and $0.639 for each pre-funded warrant and accompanying common warrant. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of common stock and were exercised in full on November 5, 2021. The warrants were immediately exercisable at a price of $0.70 per share of common stock and expire five years from the date of issuance. No warrants have been exercised as of December 31, 2021.

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H.C. Wainwright & Co., LLC also exercised its over-allotment option, pursuant to the underwriting agreement, to purchase an additional 3,515,625 shares of common stock and 3,515,625 warrants to purchase common stock at the public offering price per share and per warrant less the underwriters' discounts and commissions. After giving effect to the sale of 3,515,625 additional shares pursuant to the exercise of the option that closed on November 9, 2021, the total number of shares of common stock (or common stock equivalents) sold by us in the offering increased to 26,953,125, together with warrants to purchase up to 26,953,125 shares of common stock issued at the closing on November 5, 2021, for total gross proceeds of $17.25 million before deducting underwriting discounts and commissions and other offering expenses, and net proceeds of approximately $15.8 million. As a result of the offering, the exercise price of the Bridge Warrants was adjusted to $0.31 per share.

Liquidity and Capital Resources

The Company has no product revenues, incurred operating losses since Inception, and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. The Company had an accumulated deficit of approximately $28.9 million at December 31, 2021, a net loss of approximately $10.6 million, and approximately $9.3 million of net cash used in operating activities for the year ended December 31, 2021.

Going Concern

The Company has evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the filing of this Annual Report. Based on such evaluation and the Company's current plans, which are subject to change, management believes that the Company's existing cash and cash equivalents as of December 31, 2021 are not sufficient to satisfy its operating cash needs for the year after the filing of this Annual Report.

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

The Company's future liquidity and capital funding requirements will depend on numerous factors, including:

- its ability to raise additional funds to finance its operations, including its ability to access financing that may be unavailable due to contractual limitations under the Securities Purchase Agreement;
- the outcome, costs and timing of clinical trial results for the Company's current or future product candidates, including the timing, progress, costs and results of its planned Phase 3 clinical trial of TMB-001 for the treatment of congenital ichthyosis as well as its ongoing Phase 2b clinical trial of TMB-002 for the treatment of facial angiofibromas in tuberous sclerosis complex;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the emergence and effect of competing or complementary products;
- its ability to maintain, expand and defend the scope of its intellectual property portfolio, including the amount and timing of any payments the Company may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- the cost and timing of completion of commercial-scale manufacturing activities if any of its products are approved for commercial sale;

- the cost of establishing sales, marketing and distribution capabilities for its products in regions where it chooses to commercialize its products on its own, if approved for commercial sale;

- the initiation, progress, timing and results of the commercialization of its product candidates, if approved for commercial sale;

- its ability to retain its current employees and the need and ability to hire additional management and scientific and medical personnel; and

- the terms and timing of any collaborative, licensing or other arrangements that it has or may establish.

The Company will need to raise substantial additional funds through one or more of the following: issuance of additional debt or equity and/or the completion of a licensing or other commercial transaction for one or more of the Company's product candidates. If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or convertible debt financings will likely have a dilutive effect on the holdings of the Company's existing stockholders.

The impact of the worldwide spread of a novel strain of coronavirus ("COVID-19") has been unprecedented and unpredictable. Site activation and patient enrollment have recently been impacted by the COVID-19 pandemic in the larger and longer TMB-002 study, especially at our contracted test sites in Western Europe. The Company is continuing to assess the effect on its operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus throughout the world and its assessment of the impact of COVID-19 may change.

Note 2. Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") as determined by the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") and include all adjustments necessary for the fair presentation of its consolidated balance sheet, results of operations and cash flows for the period presented.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's consolidated financial statements relate to the valuations of warrants, notes, and equity-based awards and member units. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. Cash and cash equivalents include cash held in banks and money market mutual funds.

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
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Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful life on a straight-line basis as follows:

- Furniture 7 years

Expenditures for maintenance and repairs which do not improve or extend the useful lives of respective assets are expensed as incurred. When assets are sold or retired, the related cost and accumulated depreciation are removed from their respective accounts and any resulting gain or loss is include income (loss) from operations.

Research and Development

Research and development costs, including in-process research and development acquired as part of an asset acquisition for which there is no alternative future use, are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Accrued Outsourcing Costs

Substantial portions of the Company's preclinical studies and clinical trials are performed by third-party laboratories, medical centers, contract research organizations and other vendors (collectively "CROs"). These CROs generally bill monthly or quarterly for services performed, or bill based upon milestone achievement. For preclinical studies, the Company accrues expenses based upon estimated percentage of work completed and the contract milestones remaining. Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as CROs, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the number of patients in the trial, the attrition rate at which patients leave the trial, and/or the period over which clinical investigators or CROs are expected to provide services. The Company's estimates depend on the timeliness and accuracy of the data provided by the CROs regarding the status of each program and total program spending. The Company periodically evaluates the estimates to determine if adjustments are necessary or appropriate based on information it receives.

Fair Value Measurement

The Company follows the accounting guidance in ASC 820 for its fair value measurements of financial assets and liabilities measured at fair value on a recurring basis. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

As of December 31, 2021, and 2020, the recorded values of prepaid expenses, accounts payable, accrued expenses, and license payable, approximate the fair values due to the short-term nature of the instruments.

Leases

The Company accounts for its leases under the Financial Accounting Standards Board Accounting Standards Codification ("ASC") 842, *Leases* ("ASC 842"). Under this guidance, arrangements meeting the definition of a lease are classified as operating or financing leases, and are recorded on the consolidated balance sheet as both a right of use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and the right of use asset is amortized over the lease term. For operating leases, interest on the lease liability and the amortization of the right of use asset result in straight-line rent expense over the lease term.

In calculating the right of use asset and lease liability, the Company elects to combine lease and non-lease components as permitted under ASC 842. The Company excludes short-term leases having initial terms of 12 months or less from the new guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

Revenue Recognition

The Company has not yet generated any revenue from product sales. The Company's source of revenue in 2021 and 2020 has been from grants. When grant funds are received after costs have been incurred, the Company records grant revenue upon the receipt of cash.

Warrant Liability

The Company had accounted for certain common stock warrants outstanding as a liability at fair value and adjusts the instruments to fair value at each reporting period. This liability was subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized in the Company's statements of operations. The Company issued Series A Warrants to purchase 8,384,764 shares of its common stock to investors in connection with the $20 million financing in May 2020, and recorded these outstanding warrants as a liability at fair value utilizing a Monte Carlo simulation model. As further described in Note 6, the fair value of the warrants issued by the Company in connection with the $5.0 million Bridge Notes has been estimated using a probability-weighted Black-Scholes option pricing model. Upon consummation of the Merger the Series B Warrants are classified as equity.

Pursuant to the waiver agreement related to the Company's Series A Warrants (see Note 1), on November 19, 2020, the warrant liability was reclassified to additional paid-in capital.

Warrants

The Company estimates the fair value of certain common stock warrants using a Black-Scholes option pricing model, and the assumptions used in calculating the fair value of such warrants represented management's best estimates and involve inherent uncertainties and the application of management's judgment. The fair value of common stock warrants has been recorded in equity as additional paid-in-capital.

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
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Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation—Stock Compensation," which requires the measurement and recognition of compensation expense based on estimated fair market values for all share-based awards made to employees and directors, including stock options. The Company expenses stock-based compensation to employees, non-employees and board members over the requisite service period based on the estimated grant-date fair value of the awards and actual forfeitures. The Company accounts for forfeitures as they occur. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the consolidated statements of operations based upon the underlying individual's role at the Company.

Convertible Preferred Stock

The Company records shares of convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs. The Company has applied the guidance in ASC 480-10-S99-3A, *Securities and Exchange Commission ("SEC") Staff Announcement: Classification and Measurement of Redeemable Securities* and therefore classified the Series A convertible preferred stock as mezzanine equity. The convertible preferred stock was recorded outside of stockholders' deficit because, in the event of certain change of control events considered not solely within the Company's control, such as a merger, acquisition and sale of all or substantially all of the Company's assets, the convertible preferred stock will become redeemable at the option of the holders. **See Note 9.**

Loss Per Share

Basic net loss per share ("EPS") of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted EPS reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity.

To calculate the basic EPS numerator, income available to common stockholders must be computed by deducting both the dividends declared in the period on preferred stock (whether or not paid) and the dividends accumulated for the period on cumulative preferred stock (whether or not declared) from income from continuing operations and also from net income. If there is a loss from continuing operations or a net loss, the amount of the loss shall be increased by those preferred dividends. The outstanding Series A Preferred Stock has cumulative dividends, whether or not declared.

The basic and diluted net loss amounts are the same for the years ended December 31, 2021 and 2020, as a result of the net loss and anti-dilutive impact of the potentially dilutive securities. Potentially dilutive shares are determined by applying the treasury stock method to the assumed exercise of outstanding stock options, value appreciation rights, and warrants. Potentially dilutive shares issuable upon conversion of the Series A Preferred Stock are calculated using the if-converted method.

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
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The following is a reconciliation of the numerator and denominator of the diluted net loss per share computations for the periods presented below:

	Year Ended December 31,	
	2021	2020
Basic and diluted loss per share:		
Net (loss) income	$ (10,639,146)	$ (15,117,614)
Accrued dividend on preferred stock units	—	(52,669)
Cumulative dividends on Series A preferred stock	(129,992)	(90,516)
Net (loss) income attributable to common stockholders	$ (10,769,138)	$ (15,260,799)
Basic and diluted weighted average number of shares outstanding	40,440,570	15,699,869
Basic and Diluted net (loss) per share attributable to common stockholders	$ (0.27)	$ (0.97)

Securities that could potentially dilute loss per share in the future were not included in the computation of diluted loss per share for the years ended December 31, 2021 and 2020, respectively , because their inclusion would be anti-dilutive are as follows:

	December 31,	
	2021	2020
Series A warrants	16,701,824	20,178,214
Bridge warrants	413,751	413,751
Value appreciation rights	359,486	367,670
Options to purchase common stock	2,696,473	184,456
Series A preferred stock	1,819	1,819
Legacy stock options	15,781	15,781
Legacy warrants	213,992	219,928
Warrants issued in the November 2021 Financing	26,953,125	—
	47,356,251	21,381,619

Income taxes

Income taxes are accounted for under the asset and liability method. Deferred income taxes are recorded for temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. Deferred tax assets and liabilities reflect the tax rates expected to be in effect for the years in which the differences are expected to reverse. A valuation allowance is provided if it is more-likely than not that some or all of the deferred tax assets will not be realized.

The Company also follows the provisions of accounting for uncertainty in income taxes which prescribes a model for the recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition. In accordance with this guidance, tax positions must meet a more-likely than not recognition threshold and measurement attribute for the financial statement recognition and measurement of tax position.

The Company’s policy is to account for income tax related interest and penalties in income tax expense in the accompanying consolidated statements of operations.

Recent accounting pronouncements

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity, which simplifies accounting for convertible instruments by removing

major separation models required under current GAAP. The ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. This ASU is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. This update permits the use of either the modified retrospective or fully retrospective method of transition. The Company is currently evaluating the impact this ASU will have on its consolidated financial statements and related disclosures.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40). This ASU reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. This ASU provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. It specifically addresses: (1) how an entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; (2) how an entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange; and (3) how an entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. This ASU will be effective for all entities for fiscal years beginning after December 15, 2021. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted, including adoption in an interim period. The adoption of ASU 2021-04 is not expected to have a material impact on the Company's financial statements or disclosures.

Note 3. Acquisition of BioPharmX

As described in Note 1, on May 18, 2020, the Company completed its acquisition of BioPharmX in accordance with the terms of the Merger Agreement. The acquisition was accounted for as an asset acquisition/reverse merger.

Pursuant to the Merger Agreement, following the Merger, the Timber Sub members, including the investors funding the $20 million investment and the bridge investors, own approximately 88.5% of the outstanding common stock of BioPharmX, and the BioPharmX stockholders own approximately 11.5% of the outstanding common stock as of the date of the merger. The cost of the BioPharmX acquisition, which represents the consideration transferred to BioPharmX stockholders in the BioPharmX acquisition, of $12.4 million consists of the following:

Number of shares of the combined company owned by BioPharmX stockholders	1,367,326
Multiplied by the fair value per share of BioPharmX common stock	$ 6.12
Total estimated fair value of common stock	8,368,033
Add: net liabilities acquired	(2,833,453)
Add: investment in BioPharmX	(1,169,846)
Total consideration - recorded as research and development acquired	**$ 12,371,332**

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The total cost of the BioPharmX acquisition was allocated to the net liabilities acquired as follows:

Cash and cash equivalents	$ 340,786
Other current assets	2,027
Deposits	114,534
ROU asset	904,370
Accounts payable	(610,882)
Credit cards	760
Accrued expenses	(148,999)
Note - short term	(2,456,614)
Operating lease liability - short term	(259,712)
Other long term liabilities	(73,682)
Operating lease liability - long term	(646,041)
Net liabilities acquired	**$ (2,833,453)**

Note 4. Credit Agreement with BioPharmX

Loan to BioPharmX

In 2020, prior to the BioPharmX acquisition the Company loaned BioPharmX $2.5 million in three tranches. During the year ended December 31, 2020, the Company recorded interest income of approximately $42,000. In connection with the loan the Company also received a warrant which was subsequently exercised for 193,596 common shares of BioPharmX.

The following is a summary of the loan and investment in BioPharmX during the year ended December 31, 2020:

	Loan to BioPharmX	Investment in BioPharmX	Total
Balance as of January 1, 2020	$ —	$ —	$ —
Principal balance	2,400,000	—	2,400,000
Accrued interest	41,655	—	41,655
Fair value of BioPharmX common stock	—	625,000	625,000
Change in fair value	—	559,805	559,805
Balance as of May 18, 2020	**$ 2,441,655**	**$ 1,184,805**	**$ 3,626,460**
Acquisition of BioPharmX	(2,456,614)	—	(2,456,614)
Loan and investment in BioPharmX - recorded as research and development license acquired	14,959	(1,184,805)	(1,169,846)
Balance as of December 31, 2020	**$ —**	**$ —**	**$ —**

Note 5. Purchases of Assets

Acquisition of Intellectual Property Rights from Patagonia Pharmaceuticals LLC ("Patagonia")

On February 28, 2019, the Company acquired the intellectual property rights to a topical formulation of isotretinoin for the treatment of congenital ichthyosis and identified as TMB-001, formerly PAT-001, from Patagonia (the "TMB-001 Acquisition").

Upon closing of the TMB-001 Acquisition, the Company paid a one-time upfront payment of $50,000 to Patagonia. Patagonia is entitled to up to $27.0 million of cash milestone payments relating to certain regulatory and commercial achievements of TMB-001, with the first being $4.0 million for the initiation of a Phase 3 pivotal trial, as agreed with the FDA. In addition, Patagonia is entitled to net sales earn-out payments ranging from low single digits to mid- double digits.

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The Company is responsible for all development activities. The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 and 2020.

On June 26, 2019, the Company acquired the intellectual property rights to a locally administered formulation of Sitaxsentan for the treatment of cutaneous fibrosis and/or pigmentation disorders, and identified as TMB-003, formerly PAT-S03, from Patagonia (the "TMB-003 Acquisition").

Upon closing of the TMB-003 Acquisition, the Company paid a one-time upfront payment of $20,000 to Patagonia. Patagonia is entitled to up to $10.25 million of cash milestone payments relating to certain regulatory and commercial achievements of TMB-003, with the first being a one-time payment of $250,000 upon the opening of an IND with the FDA. In addition, Patagonia is entitled to net sales earn-out payments ranging from low to mid-single digits. The Company is responsible for all development activities. The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 and 2020.

The TMB-001 Acquisition and TMB-003 Acquisition were accounted for as an asset acquisition as the majority of the fair value of the assets acquired were concentrated in a group of similar assets, and the acquired assets did not have outputs or employees. Because the assets had not yet received regulatory approval, the purchase price paid for these assets was recorded as research and development expense in the Company’s statement of operations for the period from Inception to December 31, 2019.

Acquisition of License from AFT Pharmaceuticals Limited ("AFT")

On July 5, 2019, the Company and AFT entered into a license agreement which provides the Company with (i) an exclusive license to certain licensed patents, licensed know-how and AFT trademarks to commercialize the Pascomer® product in the United States, Canada and Mexico and (2) a co-exclusive license to develop the Pascomer® product in this territory. Concurrently, the Company granted to AFT an exclusive license to commercialize the Pascomer® product outside of the Company’s territory and co-exclusive sublicense to develop and manufacture the licensed product for commercialization outside of the Company’s territory (the "AFT License Agreement").

The AFT License Agreement also provides for the formation of a joint steering committee to oversee, coordinate and review recommendations and approve decisions in respect of the matters the development and commercialization of the Pascomer® product, in which both the Company and AFT have the right to appoint two members. The committee is currently comprised of three members. We have final decision-making authority on all matters relating to the commercialization of the Pascomer® product in the specified territory and on all matters related to the development (and regulatory approval) of the Pascomer® product, with certain exceptions.

The development of the Pascomer® product is being conducted pursuant to a written development plan, written by AFT and approved by the joint steering committee, which is reviewed on at least an annual basis. AFT shall perform clinical trials of the Pascomer® product in the specified territory and shall perform all CMC (chemistry, manufacturing and controls) and related activities to support regulatory approval. The Company is responsible for all expenses incurred by AFT during the term of the AFT License Agreement and shall equally share all costs and expenses with AFT, incurred by AFT for development and marketing work performed in furtherance of regulatory approval and commercialization worldwide, outside of the specified territory. The Company is entitled to receive 50% of the economics (royalties and milestones) in any licensing transaction that AFT executes outside of North America, Australia, New Zealand, and Southeast Asia. The Company received an upfront milestone payment paid to AFT by Desitin recorded approximately $0.3 million in milestone revenue for the year ended December 31, 2021.

Pursuant to the AFT License Agreement, the Company is obligated to reimburse AFT for previously spent development costs, subject to certain limitations, and to pay a one-time, irrevocable and non-creditable upfront payment to AFT, payable in scheduled installments. Specifically, the Company paid $0.25 million in October 2019 and the remaining $0.75 million due in quarterly installments with the last payment on July 1, 2020. AFT is entitled to up to $25.5 million of cash milestone payments relating to certain regulatory and commercial achievements TMB-002, with the first payment of $1.0 million upon the successful completion of a Phase 2b trial where the results of such clinical trial meet the clinical trial’s primary

clinical endpoints. In addition, AFT is entitled to net sales royalties ranging from high single digits to low double digits for the program licensed. The potential regulatory and commercial milestones are not yet considered probable, and no milestone payments have been accrued at December 31, 2021 and 2020, respectively.

Note 6. Fair Value Measurements

Bridge Warrants

During the year ended December 31, 2020, in connection with the Bridge Notes, the Company assumed a warrant obligation to purchase shares of the Company's common stock. Each warrant was exercisable into a number of shares of $0.001 par value common stock of BioPharmX, and had a term of 5 years from the closing date of the Merger (See Note 8). The warrant obligation was recognized as a Level 3 liability on the funding dates and adjusted to fair value. Upon issuance of the warrant on May 18, 2020, the warrant liability was reclassified to equity.

The inputs using the probability Black-Scholes model to calculate the fair value of the warrants related to the Bridge Notes are as follows:

	For the period January 28, 2020 - May 18, 2020
Dividend yield	—
Expected price volatility	84.9%
Risk free interest rate	0.38% - 1.48%
Expected term	5.0 - 5.3 years

Series A Warrants

On June 2, 2020, in connection with the Merger Agreement, the Company issued Series A Warrants with an initial exercise price of $2.7953 per share, are immediately exercisable upon issuance, and have a term of five years from the date of issuance. The Series A Warrants were initially exercisable for 8,384,764 shares of common stock in the aggregate.

On November 19, 2020, in connection with the Series A Warrants waiver agreements (see Note 1), the number of shares of common stock underlying the Series A Warrants was set at 20,178,214 and have a set exercise price of $1.16 per share.

The inputs using the Monte Carlo simulation model in measuring the Company's Series A Warrants at the issuance date of June 2, 2020 and during the year ended December 31, 2020, are as follows:

	June 2, 2020	Year Ended December 31, 2020
Dividend yield	—	—
Expected price volatility	78.2%	78.8% - 81.6%
Risk free interest rate	0.32%	0.26% - 0.35%
Expected term (in years)	5.0	4.5

The warrants were classified as liabilities and measured at fair value on the issuance date, with subsequent changes in fair value recognized as other expense on the consolidated statement of operations. As of December 31, 2020, the warrant liability was reclassified to equity.

Unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category.

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The following table presents changes in Level 3 liabilities measured at fair value for the year ended December 31, 2020:

	Bridge Warrants	Series A Warrants	Total
Balance at January 1, 2020	**$ —**	**$ —**	**$ —**
January 28, 2020 - First closing issuance	929,899	—	929,899
February 14, 2020 - Second closing issuance	981,557	—	981,557
March 13, 2020 - Third closing issuance	1,021,262	—	1,021,262
Sub-total	2,932,718	—	2,932,718
Issuance of Series A warrants	—	16,511,634	16,511,634
Change in fair value	490,486	(8,647,256)	(8,156,770)
Reclassification of bridge warrants to equity	(3,423,204)	—	(3,423,204)
Reclassification of Series A warrants to equity	—	(7,864,378)	(7,864,378)
Balance at December 31, 2020	**$ —**	**$ —**	**$ —**

The Series A warrants were reclassified to equity as of December 31, 2020; therefore there were no changes in 2021.

November 2021 Warrants

In connection with our common stock offering in November 2021, we sold in conjunction with the common stock, warrants to purchase up to 26,953,125 shares of common stock with an exercise price of $0.70 per share of common stock. The warrants were issued at the closings on November 5 and November 9, 2021, respectively. No warrants have been exercised as of December 31, 2021.

The warrants issued by the Company were recorded as equity and recognized at fair value which was approximately $8.1 million. The value of the warrants issued by the Company in connection with November 2021 Offering, were estimated using a Black Scholes option pricing model. The inputs using the Black Scholes model to calculate the fair value of the warrants related to the November 2021 offering included no dividend yield, expected price volatility of 73.1%, a risk-free interest rate of 1.05%-1.08% and an expected term of 5 years.

Note 7. Accrued Expenses

The Company's accrued expenses consisted of the following:

	December 31, 2021	December 31, 2020
Research and development	$ 77,118	$ 158,911
Professional fees	210,343	142,599
Personnel expenses	502,180	438,722
Other	60,916	28,429
Total	**$ 850,557**	**$ 768,661**

Note 8. Bridge Notes Payable

In connection with the Merger Agreement and the Credit Agreement, Timber entered into a Securities Purchase Agreement, dated as of January 28, 2020 (the "SPA") with certain institutional investors (the "Buyers"), pursuant to which the Buyers agreed to purchase, and Timber agreed to issue, senior secured promissory notes (the "Bridge Notes") from Timber in the aggregate principal amount of $5 million, in exchange for an aggregate purchase price of $3.75 million, representing aggregate discount of $1.25 million. Timber also agreed to reimburse the Buyer's representative $50,000 in transaction costs. The Company was also obligated to issue warrants to the Buyers (as further discussed below) In the quarter ended March 31, 2020, the Company received a total of $3.7 million. The Bridge Notes bear interest at a rate of 15% per annum (25% upon the occurrence of an event of default thereunder) and are repayable upon the earlier of (i) the closing of a fundamental transaction of Timber, (ii) the date on which Timber's equity is registered under the Securities

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Exchange Act of 1934, as amended or is exchanged for equity so registered the Public Company Date or (iii) July 28, 2020. The Bridge Notes and any unpaid interest are automatically exchangeable into securities issued pursuant to the Securities Purchase Agreement, described in Note 1, based on the per share price received from investors in the Securities Purchase Agreement, which was $6.0423, per share. The Company issued 827,499 shares to settle the Bridge Notes.

In connection with the SPA, the Company was obligated, within five trading days following the consummation of the first capital raising transaction, post-Merger (see Note 1), to issue to the Buyers, warrants to purchase a total number shares of common stock that equates to 100% of the as-converted shares, as if the Bridge Notes were convertible at the lowest price any securities are sold, convertible or exercisable into in the Timber Funding or the next round of financing. Each warrant would be exercisable into a number of shares of $0.001 par value common stock of BioPharmX, and have a term of 5 years from the closing date of the Merger. The warrants do not meet the scope exception of ASC 815, *Derivative Accounting*, and therefore, have been accounted for as a liability. The warrant liability had initially been recorded at the fair value on the date the Company became obligated to issue the warrants (each closing date of the Bridge Notes), with subsequent changes in fair value recognized at each reporting period end date (See Note 6). There was no change in fair value of the warrants recognized during the year ended December 31, 2020, the Company recorded approximately $0.6 million as the change in fair value of the warrants as reflected in the consolidated statement of operations.

The Company recorded the debt less its discount and less the fair value of the warrant liability. Pursuant to the Merger Agreement, as of May 18, 2020, the Company reclassified its Bridge Notes and related warrant liability to equity. The following table reflects the activity related to the Company's Bridge Notes during the year ended December 31, 2020 and as of December 31, 2020:

	Bridge Notes Payable
Balance at January 1, 2020	**$ —**
January 28, 2020 - First closing issuance	1,666,666
February 14, 2020 - Second closing issuance	1,666,667
March 13, 2020 - Third closing issuance	1,666,667
Original issue discount	(1,300,000)
Discount resulting from allocation of proceeds to warrant liability	(2,932,718)
Sub-total	767,282
Amortization of debt discount	4,232,718
Reclassification of bridge note to equity	(5,000,000)
Balance at December 31, 2020	**$ —**

The debt discount resulting from the allocation of proceeds to the warrant liability was amortized through interest expense during the year ended December 31, 2020.

The inputs used to calculate the fair value of the warrants using the probability Black-Scholes model are as follows:

	For the period January 28, 2020-May 18, 2020
Dividend yield	—
Expected price volatility	84.9%
Risk free interest rate	0.38% - 1.48%
Expected term	5.0 - 5.3 years

Note 9. Temporary Equity, and Members' and Stockholder's Equity

The Company entered into a Merger Agreement with BioPharmX and effective May 18, 2020, the Company converted its common and preferred units into shares of common and preferred stock.

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Common Stock

On May 18, 2020, immediately prior to the Merger, the Company filed an amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a Reverse Stock Split. As a result of the Reverse Stock Split, the number of issued and outstanding shares of common stock immediately prior to the Reverse Stock Split was reduced into a smaller number of shares, such that every 12 shares of common stock held by a stockholder of the Company immediately prior to the Reverse Stock Split were combined and reclassified into one share of common stock after the Reverse Stock Split. All outstanding and unexercised warrants to purchase shares of common stock otherwise remain in effect pursuant to their terms, subject to adjustment to account for the Reverse Stock Split. Immediately following the Reverse Stock Split there were approximately 1,367,326 shares of common stock outstanding prior to the Merger. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise would be entitled to receive fractional shares instead received cash in lieu of their fractional shares.

Under the terms of the Amended Merger Agreement, the Company issued shares of common stock to the holders of common units. The 9,000 common units issued to TardiMed have been converted into 5,666,152 shares of common stock, and the 1,000 common units issued to Patagonia have been converted into 629,572 shares of common stock.

On May 18, 2020, pursuant to the Merger Agreement (see Note 1), 1,367,326 shares of common stock were issued for the acquisition of BioPharmX (see Note 4), with a fair value of approximately $8.4 million or $6.12 per share.

On May 18, 2020, pursuant to the Merger Agreement, 4,186,625 shares of common stock were issued to the investors of the $20 million private placement financing (See Note 1), aggregate net proceeds received totaled $17.5 million) and to settle the $5 million Bridge Notes.

On November 2, 2021, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC, as representative of the several underwriters named in Schedule I thereto, relating to the public offering, issuance and sale of 21,325,000 shares of our common stock and, to certain investors, pre-funded warrants to purchase 2,112,500 shares of common stock, and accompanying warrants to purchase up to an aggregate of 23,437,500 shares of our common stock. Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $0.64 and $0.639 for each pre-funded warrant and accompanying common warrant. The pre-funded warrants were immediately exercisable and were exercised in full on November 5, 2021. The warrants were immediately exercisable at a price of $0.70 per share of common stock and expire five years from the date of issuance.

H.C. Wainwright & Co., LLC also exercised its over-allotment option, pursuant to the underwriting agreement, to purchase an additional 3,515,625 shares of common stock and 3,515,625 warrants to purchase common stock at the public offering price per share and per warrant less the underwriters' discounts and commissions. After giving effect to the sale of 3,515,625 additional shares pursuant to the exercise of the option that closed on November 9, 2021, the total number of shares of common stock (or common stock equivalents) sold by us in the offering increased to 26,953,125, together with warrants to purchase up to 26,953,125 shares of common stock issued at the closing on November 5, 2021. No warrants have been exercised as of December 31, 2021.

Series A Warrants

Pursuant to the Securities Purchase Agreement, the Company issued 8,384,764 Series A Warrants to purchase shares of common stock. The Series A Warrants have a 5-year term and an exercise price of $2.7953, subject to the number of shares and exercise price being reset based on the Company's stock price after the Merger. The Series A Warrants were initially exercisable into 8,384,764 shares of Common Stock issued to the Investors, subject to certain adjustments.

On November 19, 2020, the Company entered into a Warrant Waiver Agreement with each of the warrant holders which modified the terms of the original agreement and eliminated further resets. The aggregate number of Series A Warrants

issued was fixed at 20,178,214 and the warrant exercise price was fixed at $1.16. As of December 31, 2021, 16,701,824 shares of common stock remain issuable upon exercise of the Series A Warrants.

Bridge Warrants

On May 22, 2020, pursuant to the Securities Purchase Agreement, the Company issued the Bridge Warrants exercisable for 413,751 shares of Common Stock in the aggregate (see Note 1). The Bridge Warrants had an exercise price of $2.2362 per share, were immediately exercisable upon issuance and have a term of five years from the date of issuance. As a result of the November 2021 Offering, the exercise price of the Bridge Warrants was adjusted to $0.31 per share. As of December 31, 2021, 413,751 shares of common stock remain issuable upon exercise of the Bridge Warrants.

Series B Warrants

The Series B Warrants had an exercise price of $0.001 per share, were exercisable upon issuance and were exercised in full on March 4, 2021. The Series B Warrants were exercisable for 22,766,776 shares of Common Stock in the aggregate.

During the year ended December 31, 2021, 7,474,033 Series B Warrants were exercised for 7,467,652 shares of the Company's common stock. The Company received no proceeds from this exercise. As of December 31, 2021, the Series B Warrants were exercised in full.

During the year ended December 31, 2020, 15,292,744 Series B Warrants were exercised for 15,284,992 shares of the Company's common stock and the Company received proceeds of $6,375.

Redeemable Series A Convertible Preferred Stock

In connection with the Merger, on May 18, 2020, the Company filed a Certificate of Designation of Preferences, Rights and Limitations (the "Certificate of Designations") with the Secretary of State of the State of Delaware that became effective immediately.

Pursuant to the Certificate of Designations, the Company designated 2,500 shares of the Company's previously undesignated preferred stock as Series A Preferred (the "Series A Preferred Stock"). The shares of Series A Preferred Stock have no voting rights. The holders of the Series A Preferred Stock are entitled to cumulative dividends from an after the date of issuance at a per annum of eight percent (8.00%) of the stated value. Dividends will be payable as and if declared by the Board out of amounts legally available therefore or upon a liquidation or redemption. Each share of Series A Preferred Stock is convertible at any time at the holder's option into a number of shares of common stock (subject to adjustment for reverse and forward stock splits, stock dividends, stock combinations and other similar transactions as specified in the Certificate of Designations) at a conversion price equal to the stated value of the Series A Preferred Stock of $1,000 (plus any accrued dividends) divided by the conversion price, or $18.054. Holders of the Series A Preferred Stock are entitled to a liquidation preference in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company. In addition, upon a Change of Control, the Series A Preferred Stock shall be redeemable for cash at the option of the holders, in whole or in part. As of December 31, 2021 and 2020, the Company accrued preferred dividends of $129,992 and $143,185 respectively, as a component of stockholder's equity.

As of May 18, 2020, pursuant to the Merger Agreement, the holder of 1,819,289 preferred units of Timber Sub outstanding immediately prior to the Merger, received 1,819 shares of newly created convertible Series A preferred stock. The Company's Series A Preferred Stock, as to which the holder has demanded redemption, was redeemable at December 31, 2021 subject to certain limitations under Delaware law, and was recorded at the redemption value of $2.1 million. Interest is accrued on the unredeemed balance at 8% annually. On November 23, 2021, the Company received a request for redemption by TardiMed for the convertible Series A Preferred Stock. The Company has asserted that such right to redemption is currently limited under Delaware corporate law. As a result of the request, the convertible Series A Preferred Stock has been reclassified as a liability, Redeemable Series A convertible preferred stock under redemption. The Series A Preferred Stock will continue to accrue dividends but as a liability, the dividends will be recorded prospectively as non-

cash interest expense in the Consolidated Statement of Operations until such time as the Series A Preferred Stock is redeemed. The redemption is payable in either cash or common shares at the Company's option. The Company recognized non-cash interest expense $15,551 during the year ended December 31, 2021 as result of the reclassification as interest is now recorded in the Consolidated Statement of Operations rather than additional-paid-in-capital.

The following table summarizes the Company's Series A Preferred Stock for the year ended December 31, 2021 and 2020, respectively:

	Series A Preferred Stock	
	Shares	Amount
Total temporary equity as of January 1, 2020	—	$ —
Conversion of preferred units to Series A preferred stock pursuant to BioPharmX acquisition	1,819	1,819,289
Cumulative dividends on Series A Preferred Stock	—	90,516
Total temporary equity as of December 31, 2020	1,819	$ 1,909,805
Cumulative dividends on Series A Preferred Stock	—	129,992
Reclass to liabilities for Redeemable Series A convertible preferred stock under redemption	(1,819)	(2,039,797)
Total temporary equity as of December 31, 2021	—	$ —

Note 10. Equity-based compensation

On May 18, 2020, the Company's 2020 Omnibus Equity Incentive Plan (the "2020 Plan") became effective, and the 2020 Plan reserved a total of 970,833 shares of common stock for issuance. The 2020 Plan provides for options to purchase shares of common stock, stock appreciation rights, restricted stock units, restricted or unrestricted shares of common stock, performance shares, performance units, incentive bonus awards, other stock-based awards and other cash-based awards. Options granted generally vest over a period of three years and have a maximum term of ten years from the date of grant. The 2020 Plan was subsequently amended in April 2021 to increase the maximum aggregate number of shares of Common Stock which may be issued to participants under the 2020 Plan to 4,668,319 shares.

Furthermore, the Company maintains its 2019 Equity Incentive Plan (the "2019 Plan"). The 2019 Plan permits the granting of incentive units (the "Incentive Units"), including Value Appreciation Rights ("VARs"). The maximum aggregate Incentive Units that may be subject to awards and issued under the Plan is 699,454.

During the years ended December 31, 2021 and 2020, stock-based compensation expenses were as follows:

	Year Ended December 31,	
	2021	2020
General and administrative value appreciation right awards	$ 42,668	$ 73,355
Research and development value appreciation right awards	1,654	(380)
General and administrative stock options	87,467	—
Research and development stock options	504,304	145,944
	$ 636,093	$ 218,919

Value Appreciation Rights

In 2019 the Company granted equity-based awards similar to stock options under the 2019 Plan as Value Appreciation Rights ("VARs"). The VARs have an exercise price, a vesting period and an expiration date, in addition to other terms similar to typical equity option grant terms. At December 31, 2021 and 2020, Incentive Units outstanding under the 2019 Plan were 359,486 and 437,553 units, respectively.

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The following is a summary of VARs issued and outstanding as of December 31, 2021 and 2020, respectively:

	Number of Units	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of January 1, 2020	437,553	$ 0.01	$ 279,077	9.4
Cancelled	(69,882)	$ 0.01	—	—
Outstanding as of December 31, 2020	367,671	$ 0.01	$ 269,502	8.4
Exercised	(8,184)	$ 1.21	—	
Outstanding as of December 31, 2021	359,487	$ 0.01	$ 136,038	7.6
Value appreciation right awards vested and exercisable at December 31, 2021	154,875	$ 0.01	$ 60,332	7.8

On January 6, 2020, 69,882 VARs were cancelled due to the voluntary termination of the Company's Chief Scientific Officer. During the year ended December 31, 2020, approximately $8,000 of compensation costs were reversed related to the cancelled VARs. No VARs were cancelled and as such there was no reversal of compensation costs during the year ended December 31, 2021.

As of December 31, 2021 and 2020, respectively, the unrecognized compensation costs were approximately $0.04 million and $0.1 million, respectively, which will be recognized over an estimated weighted-average amortization period of 1.1 years.

Stock Options

During the year ended December 31, 2021 and 2020, the Company granted 2,512,017 and 232,996 options, respectively, to purchase shares of the Company's common stock to employees and board members. The following is a summary of the options outstanding as of December 31, 2021and 2020, respectively:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2020	—	$ —	—	$ —
Granted	232,996	$ 2.87	9.4	—
Canceled	(48,540)	$ 2.87	-	—
Outstanding as of December 31, 2020	184,456	$ 2.87	9.7	$ —
Granted	2,512,017	$ 0.96	9.6	$ —
Outstanding at December 31, 2021	2,696,473	$ 1.09	9.6	
Exercisable at December 31, 2021	257,175	$ 1.57	9.3	$ —

During the year ended December 31, 2020, 48,540 options to purchase shares of the Company's common stock were canceled due to the voluntary termination of two of the Company's employees. During the year ended December 31, 2020, approximately $18,000 of compensation costs were reversed related to the cancelled options. There were no options canceled during the year ended December 31, 2021.

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As part of the Merger, the Company assumed the following legacy stock options and warrants:

	Shares Underlying Options and Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Legacy BioPharmX options - December 31, 2020	15,781	$ 75.27	2.3	$ —
Legacy BioPharmX options - December 31, 2021	15,781	$ 75.27	1.4	$ —
Legacy BioPharmX warrants - December 31, 2020	219,928	$ 164.09	2.7	$ —
Expired	(5,936)	$ 358.78	—	—
Legacy BioPharmX warrants - December 31, 2021	213,992	$ 87.21	1.8	$ —

The fair value of stock option grants are estimated on the date of grant using the Black-Scholes option-pricing model. The Company was historically a private company and lacked company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies. Additionally, due to an insufficient history with respect to stock option activity and post-vesting cancellations, the expected term assumption for employee grants is based on a permitted simplified method, which is based on the vesting period and contractual term for each tranche of awards. The mid-point between the weighted-average vesting term and the expiration date is used as the expected term under this method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following are the key assumptions used to estimate the fair value of the stock options granted during the year ended December 31, 2021 and 2020:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Expected life	5-7 years	5-7 years
Expected volatility	70.6% - 73.3%	79.0%
Risk-free interest rate	0.79% - 1.40%	0.3%
Expected dividend yield	—	—

As of December 31, 2021, the unrecognized compensation costs related to stock options were approximately $1.1 million, which will be recognized over an estimated weighted-average amortization period of 1.3 years.

Note 11. Income taxes

The components of earnings before income taxes for the years ended December 31, 2021 and 2020 were as follows:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Income (loss) before income taxes:		
Domestic	$ (10,282,676)	$ (14,839,605)
Foreign	(386,712)	(240,167)
	$ (10,669,388)	$ (15,079,772)

TIMBER PHARMACEUTICALS, INC. & SUBSIDIARIES
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The provision for income taxes for the years ended December 31, 2021 and 2020, were as follows:

	December 31, 2021	December 31, 2020
Current:		
US Federal	$ —	$ —
US State	7,600	—
Total current provision	7,600	—
Deferred:		
US Federal	—	—
US State	—	—
Foreign	(37,842)	37,842
Total deferred provision	(37,842)	37,842
Total provision for income taxes	$ (30,242)	$ 37,842

A reconciliation of the statutory income tax rates and the Company's effective tax rate is as follows:

	December 31, 2021	December 31, 2020
Statutory federal income tax rate	21.0 %	21.0 %
State taxes, net of federal tax benefit	6.0 %	5.5 %
Foreign rate differential	0.7 %	(0.1)%
Non-taxable entity	— %	(6.0)%
Change in FV of warrant liability	— %	11.8 %
Convertible note interest	— %	(4.6)%
Permanent Items	(1.0)%	— %
Other	(2.8)%	0.2 %
Change in valuation allowance	(23.6)%	(28.2)%
Income taxes provision (benefit)	0.3 %	(0.4)%

The tax effects of the temporary differences and carry forwards that give rise to deferred tax assets and liabilities consist of the following:

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operating loss	$ 27,298,015	$ 24,411,375
Research and Development Credits	1,374,264	1,374,264
Fixed assets	—	—
Intangible assets	3,254,079	3,784,755
Impairment Loss	20,296	21,654
Stock compensation	323,486	290,904
Deferred lease liability	173,528	216,154
Other	—	—
Total deferred income tax assets	32,443,668	30,099,106
Less: Valuation allowance	(32,276,429)	(29,757,796)
Deferred tax assets, net	167,239	341,310
Deferred income tax liabilities:		
Deferred lease assets	(166,947)	(213,274)
Other	(292)	(165,878)
Total deferred income tax liabilities	(167,239)	(379,152)
Deferred tax, net	$ —	$ (37,842)

In assessing the realizability of the net deferred tax assets, the Company considers all relevant positive and negative evidence to determine whether it is more likely than not that some portion of the deferred income tax will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. At December 31, 2021 and 2020, the Company has recorded a full valuation allowance against its net deferred tax assets of approximately $32.3 million and $29.8 million, respectively.

Prior to the acquisition of BioPharmX on May 18, 2020, the Company was treated as a partnership for the federal and state income tax purposes.

As of December 31, 2021, the Company had federal net operating loss ("NOL") carryforwards of approximately $94.2 million (including $80.4 million of NOL's acquired from BioPharmX), $71.3 million of California net operating loss, and a $16.7 million New Jersey net operating loss, available to reduce future taxable income, if any, for federal and state income tax purposes. The federal NOL will be carried forward indefinitely. The state net operating loss carryforwards will begin to expire in 2040. As of December 31, 2021, the Company has research and development credit carryforwards of approximately $0.65 million and California research and development credit carryforwards of approximately $0.7 acquired from BioPharmX available to reduce future taxable income subject to expiration.

Under the Internal Revenue Code ("IRC") Section 382, annual use of the Company's net operating loss carryforwards to offset taxable income may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such limitations have been triggered as of December 31, 2021. The Company has no income tax affect due to the recognition of a full valuation allowance on the expected tax benefits of future loss carry forwards based on uncertainty surrounding realization of such assets.

On December 22, 2017, the U.S. enacted comprehensive tax legislation (the "Tax Act"). Under the Tax Act, federal NOLs generated after December 31, 2017, are carried forward indefinitely for US federal income tax purposes. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was enacted and signed into law, and GAAP requires recognition of the tax effects of new legislation during the reporting period that includes the enactment date. The CARES Act, among other things, includes changes to the tax provisions that benefits business entities and makes certain technical corrections to the 2017 Tax Cuts and Jobs Act, including, permitting net operating losses, or NOLs, carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The CARES Act provides other reliefs and stimulus measures. We have evaluated the impact of the CARES Act, and do not expect that any provision of the CARES Act would result in a material cash benefit to us or have a material impact on our financial statements or internal controls over financial reporting.

The Company has not identified any uncertain tax positions requiring a reserve as of December 31, 2021 and 2020. The Company's policy is to recognize interest and penalties that would be assessed in relation to the settlement value of unrecognized tax benefits as a component of income tax expense. The Company did not accrue either interest or penalties for the year ended December 31, 2021 and 2020.

The Company files income tax returns in the U.S. federal jurisdiction and several states. Given that the company has incurred tax losses in most years since its inception, all of the Company's tax years are effectively open to examination.

Note 12. Commitments and contingencies

Leases

In connection with the Merger of BioPharmX, the Company acquired a lease and corresponding sublease for the BioPharmX facility in San Jose, California. The sublease is to be used for general office and research laboratory purposes,

has an effective date of February 1, 2020, and has a lease term of 4 years which expires on December 30, 2023. The lease expense is significantly reduced by the payments received in connection with the sublease.

The components of lease expense were as follows:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating leases:		
Operating lease cost	$ 383,558	$ 192,115
Variable lease cost	108,071	57,013
Operating lease expense	$ 491,629	$ 249,128
Lease income - sub lease	(424,759)	(206,614)
Net rent expense	$ 66,870	$ 42,514

Other information:

	Year Ended December 31, 2021	Year Ended December 31, 2020
Operating cash flows - operating leases	$ 368,050	$ 182,441
Right-of-use assets obtained in exchange for operating lease liabilities	$ 122,809	$ 904,370
Weighted-average remaining lease term – operating leases	1.9	3.0
Weighted-average discount rate – operating leases	14.1 %	15.0 %

As of December 31, 2021, future minimum payments for the lease are as follows:

	Operating Leases
Year Ended December 31, 2022	$ 406,506
Year Ended December 31, 2023	357,599
Total	$ 764,105
Less present value discount	(100,136)
Operating lease liabilities	$ 663,969

Litigation

The Company is not currently a party to any legal or governmental regulatory proceedings, nor is management aware of any pending or threatened legal or government regulatory proceedings proposed to be initiated against the Company that would have a material adverse effect on the Company's business, financial condition or operating results.

From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assess its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict; therefore, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

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Note 13. Related party transactions

Patagonia

Patagonia is a private, family-owned company founded in 2013 to address the medical needs of people with rare and serious dermatological conditions. On February 28, 2019 and June 26, 2019, the Company acquired the TMB-001 and TMB-003 licenses from Patagonia (see Note 3 for the payment terms and more details), respectively. The Chief Operating Officer, Executive Vice-President and Secretary of the Company is also the President of Patagonia. On February 27, 2019, the Company issued 1,000 founder common units to Patagonia for $10. As of December 31, 2019, Patagonia held 1,000 common units which represented 10% of the total voting units outstanding. During the year ended December 31, 2020, the 1,000 common units were converted to 629,572 shares of the Company's common stock in connection with its merger with BioPharmX (See Note 1). As of December 31, 2021 and 2020, respectively, Patagonia owns 45 shares of the Company's common stock.

TardiMed

The former Chairman of the Board of the Company is a Managing Member of TardiMed. Our former Chief Operating Officer, Executive Vice President and Secretary is a partner of TardiMed. Our Chief Financial Officer and Executive Vice President of the Company was also a former partner of TardiMed. As of December 31, 2021 and December 31, 2020 TardiMed holds 3,109,067 and 5,437,517 shares of common stock, respectively. Such shares represented less than 5% of the total voting shares outstanding at December 31, 2021 and 20% of the total voting shares outstanding at December 31, 2020. During the year ended December 31, 2020, TardiMed contributed $0.1 million in exchange for 142,392 preferred units. In connection with the Merger Agreement, these preferred units and dividends have converted into 1,819 shares of Series A preferred stock. The Company reimbursed TardiMed $99,569 and $400,346 for management fees and reimbursed expenses for the years ended December 31, 2021 and 2020, respectively.

Note 14. Subsequent events

The Company has evaluated its subsequent events from December 31, 2021 through the date these consolidated financial statements were issued and has determined that there are no subsequent events requiring disclosure in these consolidated financial statements other than the items noted below.

On March 4, 2022, Zachary Rome stepped down from his positions as the Chief Operating Officer and Executive Vice-President of the Company. As a result of his resignation, Mr. Rome (i) was entitled to 79,326 shares of common stock underlying vested VARs, or $22,528, at the Company's election, and (ii) forfeited 52,884 VARs. Mr. Rome continues to serve on the Company's Board of Directors. On March 4, 2022, Mr. Rome received 59,696 shares of common stock net upon exercise of the VARs after tax withholding.

Exhibit 21.1

SUBSIDIARIES OF TIMBER PHARMACEUTICALS, INC.

As of December 31, 2021, Timber Pharmaceuticals, Inc.'s subsidiaries are as follows:

- BioPharmX, Inc. (Nevada corporation)
- Timber Pharmaceuticals Australia Pty Ltd. (Australian proprietary limited company)
- Timber Pharmaceuticals LLC (Delaware LLC)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-262391, 333-259830, 333-239216, 333-227262, 333-217419, 333-213627 and 333-201708) on Form S-8 and (Nos. 333-255743, 333-251138, 333-220012, 333-213635 and 333-212015) on Form S-3 of Timber Pharmaceuticals, Inc. and subsidiaries of our report dated March 31, 2022, with respect to the consolidated financial statements as of December 31, 2021 of Timber Pharmaceuticals, Inc.

/s/ KPMG LLP

Short Hills, New Jersey
March 31, 2022

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Koconis, certify that:

1. I have reviewed this report on Form 10-K of Timber Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

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

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

/s/ John Koconis

John Koconis
Chief Executive Officer
(Principal Executive Officer)
March 31, 2022

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Lucchese, certify that:

1. I have reviewed this report on Form 10-K of Timber Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

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

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

/s/ Joseph Lucchese
Joseph Lucchese
Chief Financial Officer
(Principal Financial and Accounting Officer)
March 31, 2022

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, John Koconis, Chief Executive Officer of Timber Pharmaceuticals, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Annual Report on Form 10-K for the period ended December 31, 2021 (the "Report") filed with the Securities and Exchange Commission:

- Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ John Koconis
John Koconis
Chief Executive Officer
(Principal Executive Officer)
March 31, 2022

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Joseph Lucchese, Chief Financial Officer of Timber Pharmaceuticals, Inc. (the "Company"), in compliance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Annual Report on Form 10-K for the period ended December 31, 2021 (the "Report") filed with the Securities and Exchange Commission:

- Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph Lucchese
Joseph Lucchese
Chief Financial Officer
(Principal Financial and Accounting Officer)
March 31, 2022