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, 2025

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: 001-37823

TUHURA BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Nevada	**99-0360497**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

10500 University Center Dr., Suite 110
Tampa, Florida 33612
(Address of principal executive offices and Zip Code)
(813) 875-6600
(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	HURA	The Nasdaq Capital Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) 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 the definitions 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 control 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

The aggregate market value of the common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market ("Nasdaq") on June 30, 2025 (the last business day of the registrant's second fiscal quarter), was $111,000,000, based on the closing price on Nasdaq reported for such date. As of March 23, 2026, there were 63,578,528 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the annual stockholder meeting to be held in 2026 are incorporated by reference into Part III of this Annual Report on Form 10-K as noted herein. The registrant intends to file its proxy statement within 120 days after its fiscal year end.

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FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K (the "Annual Report") 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 (the "Exchange Act"), 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 ability to raise funds for general corporate purposes and operations, including our research activities and clinical studies;
- our ability to realize the anticipated benefits of our merger (the "Kineta Merger") with Kineta, Inc. ("Kineta");
- the effects of the Kineta Merger on our business relationships, operating results and business generally;
- expectations regarding strategies, prospects, plans, expectations and objectives of our management for future operations of our company following the closing of the Kineta Merger
- unexpected costs, charges or expenses resulting from the Kineta Merger:
- our ability to recruit qualified management and technical personnel;
- the cost, timing, scope and results of our clinical studies;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our ability to attract and retain key scientific, medical, commercial and management personnel;
- our ability to obtain and maintain required regulatory approvals for our products;
- our expectations regarding the use of our existing cash;
- the therapeutic potential of IFx-Hu2.0, TBS-2025 and future product candidates;
- the regulatory approval processes of the U.S. Food and Drug Administration and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, such product candidates, and our ability to generate revenue will be materially impaired;
- our ability to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned products;
- our ability to develop and commercialize products without infringing the intellectual property rights of third parties; and
- the other factors discussed in the *"Risk Factors"* section and elsewhere in this Annual Report.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified in Part I, Item 1A. "*Risk Factors*" and Part II, Item 7. "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" in this Annual Report.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Annual Report and the documents that we reference in this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we have no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Note Regarding Company References; Trademarks

In this Annual Report, references to the "Company," "we," "us," "our" or similar terms refer to TuHURA Biosciences, Inc., a Nevada corporation, together with its consolidated subsidiaries.

This Annual Report includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

PART I

Item 1. Business

Overview

We are a phase 3 clinical stage immuno-oncology company with three distinct technologies focused on the development of novel therapeutics designed to overcome primary and acquired resistance to cancer immunotherapies.

Our proprietary Immune FxTM technology platform, or IFx, is an innate immune agonist technology designed to "trick" the body's immune system to attack tumor cells by making tumor cells look like bacteria. Our lead product candidate, IFx2.0, is an innate immune agonist designed to overcome primary resistance to checkpoint inhibitors. In June 2025, we initiated a single randomized placebo-controlled Phase 3 registration trial of administered as an adjunctive therapy to Keytruda® (pembrolizumab) in first line treatment for patients with advanced or metastatic Merkel cell carcinoma who are checkpoint inhibitor naïve utilizing the FDA's accelerated approval pathway.

In addition to our IFx technology platform, in June 2025 we acquired the rights to TBS-2025, a novel VISTA-inhibiting monoclonal antibody formerly known as KVA1213, through our acquisition of Kineta, Inc. ("Kineta") on June 30, 2025. VISTA (otherwise referred to as V-domain Ig suppressor of T cell activation) is an immune checkpoint highly expressed on myeloid cells that is believed to be a strong driver of immunosuppression in the tumor microenvironment and is believed to be a primary mechanism by which leukemic blasts escape immune recognition contributing to low response rates and high rates of recurrence in acute myeloid leukemia, or AML. Following our acquisition of Kineta, we are currently planning on investigating TBS-2025 in a Phase1b/2 trial in patients with r/r *mut*NPM1AML.

In addition to our IFx and TBS-2025, we are leveraging our Delta Opioid Receptor (DOR) technology to develop first-in-class bi-functional, bi-specific antibody-drug conjugates ("ADCs") targeting the DOR on Myeloid Derived Suppressor Cells ("MDSCs") to modulate their immunosuppressive influence on the bone marrow and tumor microenvironment to prevent T cell exhaustion and acquired resistance to checkpoint inhibitors and cellular therapies.

Our History and Team

We are a Nevada corporation originally formed on June 24, 2009 under the name Berry Only Inc. On January 25, 2013, we entered into and closed an exchange agreement, with Del Mar Pharmaceuticals (BC) Ltd. ("Del Mar (BC)"), 0959454 B.C. Ltd., and 0959456 B.C. Ltd. and the security holders of Del Mar (BC). Upon completion of the exchange agreement, Del Mar (BC) became our wholly-owned subsidiary. On August 19, 2020, we completed a merger with Adgero Biopharmaceuticals Holdings, Inc., a Delaware corporation ("Adgero"), in which Adgero continued its existence under Delaware law and became our direct, wholly-owned subsidiary. Following the completion of the merger, we changed our name from Del Mar Pharmaceuticals, Inc. to Kintara Therapeutics, Inc. ("Kintara") and began trading on Nasdaq under the symbol "KTRA."

On October 18, 2024, Kintara completed its reverse merger transaction in accordance with the terms of the Agreement and Plan of Merger, dated as of April 2, 2024 (the "Kintara Merger Agreement"), by and among Kintara, TuHURA Biosciences, Inc. ("Legacy TuHURA"), and Kayak Mergeco, Inc., a direct wholly owned subsidiary of Kintara ("Merger Sub"). Pursuant to the Kintara Merger Agreement, Merger Sub merged with and into Legacy TuHURA, with Legacy TuHURA surviving the merger and becoming our direct, wholly-owned subsidiary (the "Kintara Merger"). Effective at 12:03 a.m. Eastern Time on October 18, 2024, the merger was completed, and effective at 12:04 a.m. Eastern Time on October 18, 2024, Kintara Therapeutics, Inc. was renamed "TuHURA Biosciences, Inc."

On June 30, 2025, we completed the acquisition via merger of Kineta, Inc. ("Kineta") pursuant to an Agreement and Plan of Merger, dated December 11, 2024, and as amended by that certain First Amendment to Agreement and Plan of Merger, dated May 5, 2025 (as amended, the "TuHURA-Kineta Merger Agreement"), by and among the Company, Hura Merger Sub I, Inc., a Delaware corporation and a direct wholly-owned subsidiary of the Company, Hura Merger Sub II, LLC, a Delaware limited liability company and direct wholly-owned subsidiary of the Company, Kineta, and Craig Philips, solely in his capacity the representative, agent and attorney-in-fact of the stockholders of Kineta. Pursuant to the terms of the TuHURA-Kineta Merger Agreement, the former stockholders of Kineta received merger consideration in the amount of an aggregate of approximately 4 million shares of Company common stock pursuant to the terms and conditions of the TuHURA-Kineta Merger Agreement, each share of Kineta common stock, par value $0.001 per share (each, a "Kineta Share"), issued and outstanding immediately prior to the First Merger, was converted into the right to receive 0.185298 shares of the Company's common stock, par value $0.001 per share, for an aggregate of approximately

2,868,169 shares of Company common stock. Also pursuant to the terms and conditions of the TuHURA-Kineta Merger Agreement, each Kineta Share received its pro rata portion of approximately 1,129,880 shares of Company common stock in December 2025, in accordance with the terms of the TuHURA-Kineta Merger Agreement. In addition, each Kineta share is entitled to the right to its pro rata share of cash consideration, if any, received in the future in the form of disposed asset payments related to legacy Kineta assets transferred prior to the merger with Kineta.

Legacy TuHURA's predecessor company was formed as Morphogenesis, Inc. in 1995 by Drs. Patricia and Michael Lawman. Our IFx technology was developed in the laboratory of Dr. Michael Lawman at the Walt Disney Memorial Cancer Institute, where Dr. Michael Lawman was formerly a Director of the Institute, and Dr. Patricia Lawman was formerly Division Director of Cancer Molecular Biology at the Institute. Dr. Michael Lawman is a Fellow of the Royal Society of Biology, former Associate Professor at University of South Florida, and former Scientific Research Director of Pediatric Hematology/Oncology at St. Joseph's Children's Hospital. Dr. Patricia Lawman also serves as an Adjunct Professor at University of South Florida. Drs. Patricia and Michael Lawman are each inventors on numerous U.S. and foreign patents.

Our Delta Opioid Receptor ADC technology was developed in the laboratory of Dr. Mark McLaughlin at the Moffitt Cancer Center and at the West Virginia University Research Corporation. Dr. McLaughlin was previously a Senior Member of the Drug Discovery Department at the Moffitt Cancer Center and previously Professor of Medicinal Chemistry and Member WVU Cancer Institute, where his research focused on protein-protein interaction inhibitor design and molecular targeted immunotherapy. The discovery that the Delta receptor is highly expressed on MDSCs was jointly discovered by scientists at Moffitt Cancer Center and TuHURA Biopharma, a separate company whose intellectual property assets we acquired in January 2023.

Our CEO, Dr. James Bianco, is a 33-year veteran of the biopharmaceutical industry. Dr. Bianco is the principal founder of CTI Biopharma, where he served as its CEO from 1992 to October 2016. Dr. Bianco's experience spans all aspects of drug development from phase I-IV clinical trials, regulatory approval, and pricing reimbursement to sales and marketing. He has extensive experience in financing, negotiating and execution of pharmaceutical development and commercial license agreements. During his tenure at CTI Biopharma, Dr. Bianco was responsible for strategic portfolio development and identifying, acquiring, licensing, purchasing, or acquiring through international merger and acquisition, five drug candidates, four of which have since been approved by the FDA and with three receiving accelerated or conditional regulatory approval in the U.S. and/or E.U. In 2013, Dr. Bianco led CTI Biopharma in the identification and negotiation of the asset purchase for VONJO® (pacritinib), a novel JAK2 selective tyrosine kinase inhibitor. He also led CTI Biopharma in the negotiation of the development and commercial license agreement with Baxalta. As CEO of CTI Biopharma, Dr. Bianco was also responsible for the PERSIST-2 Phase 3 trial design and conduct, the successful results of which served as the basis for the 2022 FDA accelerated approval of Vonjo® (pacritinib) and the subsequent acquisition of CTI Biopharma by SOBI for $1.75 billion.

IFx Innate Immune Agonist Development Program

We have developed Immune Fx™, or IFx, as an innate immune agonist technology designed to "trick" the body's immune system to attack tumor cells by making tumor cells look like bacteria and to thereby harness the natural power of innate immunity by leveraging natural mechanisms conserved throughout evolution to recognize threats from foreign pathogens like bacteria or viruses. Our innate immune agonist product candidates are delivered either via intratumoral injection (in the case of the Company's pDNA innate immune agonist) or tumor-targeted via intravenous or autologous whole-cell administration (in the case of our mRNA innate immune agonist).

Our IFx-2.0 innate immune agonist, our lead product candidate, is comparatively simple to administer and involves only the injection into a patient's tumor, or lymph node, of a relatively small amount of pDNA that is designed to encode for an immunogenic gram positive bacterial protein that gets expressed on the surface of the patient's tumor so that the surface of the tumor looks like a bacterium.

Bacteria, like all pathogens, have molecular patterns or motifs that are conserved through evolution and that are recognized by specific pattern-recognition receptors on immune cells of our innate immune system. This is an individual's primary line of defense against pathogens that the individual is born with, and the innate immune system has no choice but to recognize the tumor as it would a gram-positive bacteria or any pathogen. Gram-positive bacterial proteins are mostly recognized by Toll Like Receptor-2 (TLR-2) on antigen presenting cells, which engulf and ingest the entire intact tumor cell packaging all the foreign tumor neoantigens presenting them to and educating tumor killing T cells and B cells. In doing so, IFx-2.0 harnesses the power of the innate immune response to produce activated tumor-specific T cells where they previously didn't exist overcoming primary resistance to checkpoint inhibitor therapy.

We have entered into a Special Protocol Assessment agreement with the FDA for a single Phase 3 randomized placebo and injection-controlled trial for IFx-2.0, our lead innate immune agonist, as an adjunctive therapy to pembrolizumab (Keytruda®) in the first line treatment of patients with advanced or metastatic Merkel cell carcinoma, who are checkpoint inhibitor-naïve utilizing the FDA's accelerated approval pathway. A Special Protocol Assessment agreement is a binding written agreement between the U.S. Food and Drug Administration (FDA) and a trial sponsor that indicates the FDA has agreed to the study's design, charters, and statistical analysis plan, and if the study endpoints are met within the context of the SPA Agreement, such results would be adequate to support accelerated and regular approval. A Special Protocol Assessment agreement does not increase the likelihood of marketing approval for the product and may not lead to a faster or less costly development, review, or approval process. We initiated the Phase 3 trial in June 2025.

In designing the Phase 3 trial for IFx-2.0, we worked with the deputy director of the FDA's Oncology Center of Excellence (OCE) on what we believe is a unique trial design. Consistent with the FDA's Project Front Runner initiative, the FDA recommended investigating IFx-2.0 in the front-line treatment setting rather than in patients who are progressing on checkpoint inhibitor therapy. In doing so, data from a primary endpoint of objective response rate, or ORR, that is of sufficient magnitude and duration and with a favorable risk/benefit profile could be sufficient to support accelerated approval. Furthermore, OCE requested that the Company consider incorporating a key secondary endpoint that is of clinical benefit such that results from a key secondary endpoint of progression-free survival, or PFS, that is adequately powered with statistical assumptions in the statistical analysis plan provided to the FDA, if achieved without a detrimental effect on overall survival, or OS, could be adequate to support conversion to regular approval satisfying the requirement for a confirmatory trial.

We anticipate that enrollment for the Phase 3 will take approximately 18 – 24 months from the initiation of the trial, with top-line data potentially being available 6 to 7 months following the last patient enrolled. If successful, this Phase 3 trial would form the basis of a Biologics License Application, or BLA.

We previously announced that we were pursuing development of a product candidate referred to as *IFx-3.0*, an mRNA innate immune agonist candidate for intravenous or autologous whole cell administration for blood- related cancers. However, with the acquisition of Kineta, we have determined not to advance the development of IFx-3.0 until the results of the IFx-2.0 Phase 3 trial in Merkel cell carcinoma are known and have reallocated resources to the below-described planned trial for TBS-2025.

TBS-2025 Development Program

As a result of our acquisition of Kineta in June 2025, we acquired the rights to TBS-2025, a novel VISTA- inhibiting monoclonal antibody formerly known as KVA1213. Unlike other checkpoints, which are mostly present on activated T cells, VISTA is predominately expressed on myeloid cells, notably MDSCs, and on quiescent T cells. Research has demonstrated that when mutated, NPM1 and DNM3TA, two of the most common mutations in AML and typically co-mutated in myelodysplasia (MDS), result in high expression of VISTA on the surface of leukemic blasts. The presence of VISTA on these cells is believed to be the primary mechanism by which leukemic cells escape immune recognition and attack, resulting in a low treatment response rate and a short duration of response in AML.

TBS-2025 was previously investigated in a dose escalation Phase 1/2 trial, both as a monotherapy and in combination with pembrolizumab, in patients with relapsed and/or treatment-refractory advanced solid tumors. TBS-2025 was well tolerated when administered every 2 weeks at doses up to 1,000mg both in the monotherapy arm (n=24) or in the pembrolizumab combination therapy arm (n=16). Pharmacokinetic and pharmacodynamic data demonstrated greater than 90% receptor occupancy across the every two- week dosing interval. Immunocytokine analysis was consistent with the mechanism of action for VISTA inhibition on immune cells.

Applying the FDA's guidelines for development of drugs in AML, the pharmacokinetic and safety data from VISTA 101, the Phase 1 study in solid tumors, can be used to determine a starting dose in a Phase 1b trial.

We anticipate conducting an abbreviated Phase1b dose escalation study in *mut*NPM1 r/r AML, which is a subtype of acute myeloid leukemia characterized by the presence of mutations in the NPM1 gene. This mutation is present in approximately 30% to 35% of cases of AML. Patients who fail or relapse following treatment with a menin inhibitor have no approved effective therapies and represent an unmet medical need population. We believe this population of patients with this genetic mutation may qualify for investigation under the FDA's Plausible Mechanism Pathway, which is a regulatory framework allowing approval based on biological rationale and target engagement rather than traditional, large randomized trials.

In addition to examining the potential of TBS-2025 monotherapy in this patient population, the Phase 1b study will also be used to establish a recommended dose to be investigated in a Phase 2 trial of TBS-2025 in combination with a menin inhibitor in *mut*NPM1 r/rAML in patients previously untreated with a menin inhibitor. The Company currently plans on discussing its development plans with the FDA late in the first half of 2026 and initiating the planned Phase1b/2 trial in as early as the second half of 2026.

DOR Technology Development Program

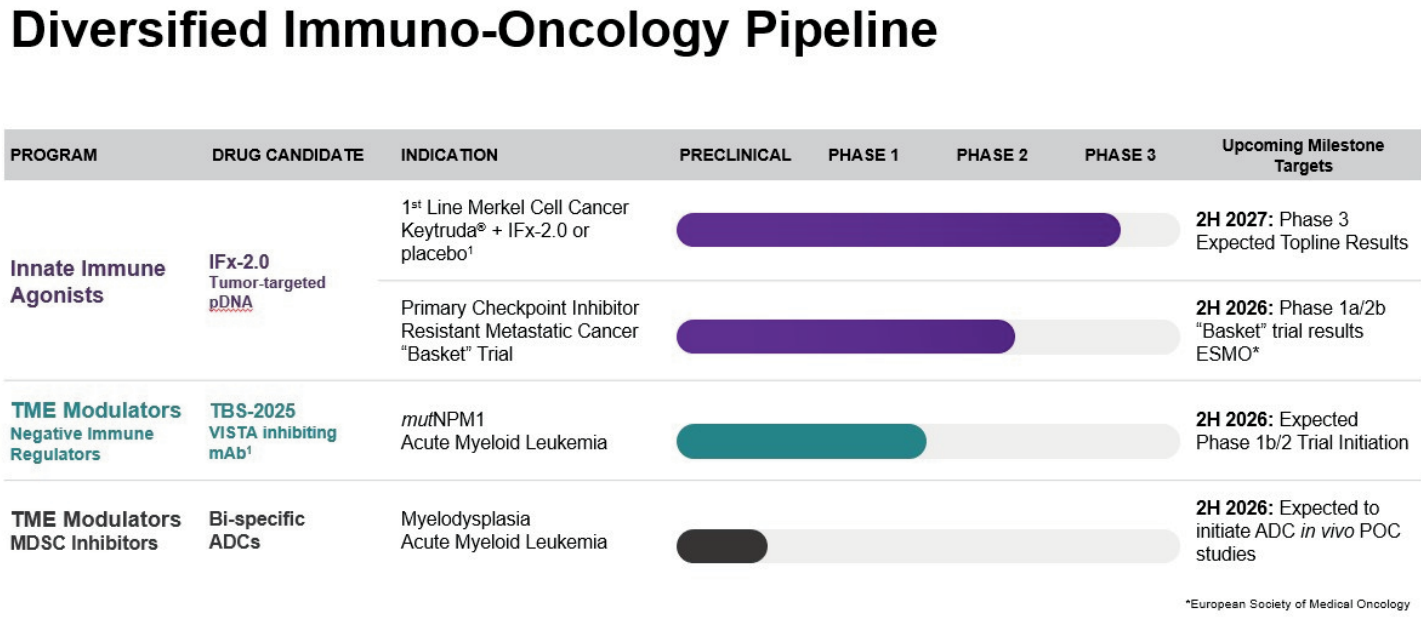
In addition to its innate immune agonist and VISTA-inhibiting product candidates, we are using proprietary Delta Opioid Receptor (DOR) technology to develop small molecule bi-specific/bi-functional immune modulating ADCs designed to inhibit the immune suppressing effects of tumor associated MDSCs on the bone marrow and tumor microenvironment to prevent T cell exhaustion and acquired resistance to checkpoint inhibitors. The Company's DOR technology was developed by scientists at Moffitt Cancer Center and TuHURA Biopharma, Inc., a separate company whose intellectual property assets we acquired in January 2023 ("TuHURA Biopharma") We believe the DOR represents a novel target to inhibit the immunosuppressive capacity of MDSCs through its control of the production of multiple immunosuppressive soluble factors, chemokines and direct cell-cell interactions.

The tumor microenvironment is the tissue surrounding a tumor, including the normal cells, blood vessels, and molecules that surround and feed a tumor cell and shield it from immune attack and eradication. MDSCs are a heterogeneous group of immature myeloid cells, which when recruited from the bone marrow to the tumor microenvironment, they transform to tumor-associated MDSCs which are characterized by their ability to suppress both innate and adaptive immune responses. Tumor associated MDSCs are generally believed to be a major contributor to T cell exhaustion (which is the loss of ability of T cells to proliferate and to kill cancer cells) and for acquired resistance to checkpoint inhibitors and cellular therapies like T cell therapies. The presence of tumor associated MDSCs in the tumor microenvironment or circulating in the bloodstream is highly correlated with poor prognosis and outcome in a wide variety of solid tumors and blood related cancers. MDSCs play a similar role in blood related cancers such as AML or Myelodysplasia (pre-leukemic syndrome) where their immune suppressing effects in the bone marrow create a permissive environment to allow leukemic cells to grow and escape immune recognition.

We believe we are the first company developing immune modulating ADCs targeting the Delta Opioid Receptor on MDSCs. We have developed a series of small molecule inhibitors of the DOR representing new molecular entities These inhibitors are highly selective (>1,000 fold) for the DOR over other opioid receptors and highly potent with IC50 (ability to inhibit 50% of DOR activity) at low nanomolar concentrations. We plan on selecting a lead compound to incorporate into our bi-specific, bi-functional ADCs, which we believe represents a paradigm shift from conventional ADCs that are currently in development or being marketed. Traditional ADCs are a class of drugs in which a monoclonal antibody is chemically linked to a "payload" such as cancer-fighting substance. The antibody carries the payload to the tumor cell, improving the selectivity of the resulting anti-cancer activity. Next generation ADCs incorporate non-chemotherapeutic technologies to interfere with tumor cell cycle growth or to carry with the antibody a checkpoint inhibitor (so called "checkpoint ADCs"). In contrast, our ADCs do not target tumor associated receptor targets, are not internalized, and do not carry a cancer fighting substances, but rather they target the Delta Opioid Receptor on MDSCs while carrying with them an immune effector to target a second receptor target like VISTA with a VISTA inhibiting antibody. These constructs result in novel bi-specific, bi-functional conjugates. They are bi-specific by targeting 2 distinct receptors (DOR and VISTA) and bi-functional by inhibiting DOR related immune suppression and checkpoint releasing resting T cells to become activated. These two functions are intended to work together with the goal of overcoming acquired resistance, preventing T cell exhaustion and allowing checkpoint inhibitors and cellular therapies to be safer and more effective while interfering with the tumor's ability to invade and spread throughout the body.

Our Pipeline

Our pipeline focuses on acquiring and developing technologies designed to overcome tumor-intrinsic mechanisms underlying primary resistance to checkpoint inhibitors. We also focus on technologies to overcome acquired resistance to cancer immunotherapies related to the immune suppressing characteristics of the tumor microenvironment. We are leveraging our technology platforms to advance several diversified product candidates, including principally the following, each of which is described in more detail below.



Our Strategy

Our goal is to become a leading immuno-oncology company by developing novel therapeutics designed to overcome primary and acquired resistance to cancer immunotherapies, thereby broadening the impact of therapies such as checkpoint inhibitors. Our strategy is focused on leveraging our current technologies and novel product candidates and development programs in order to advance our current product candidates and expand our portfolio of products and technologies. The key elements of this strategy include:

- ***Shortening the time and cost to product registration***. We are working to shorten the time and cost to product registration by focusing on patient populations that qualify for accelerated approval, such as patients with advanced and metastatic Merkel cell carcinoma in our Phase 3 trial for IFx-2.0. We believe this trial could significantly reduce the time and cost to potential approval and the cost associated with precluding the need for a postmarketing confirmatory trial.

- ***Acquire and develop novel immunomodulatory technologies or product candidates blood related cancers.*** Currently there are no cancer immunotherapies approved in blood-related cancers like AML or MDS, which presents an opportunity to develop novel agents to address such unmet medical needs. We believe we are uniquely positioned to identify, evaluate and potentially acquire novel drug candidates that focus on blood-related cancers that provide a strategic fit within our product pipeline and or with our DOR technology platforms. Our acquisition of TBS-2025 is consistent with this acquisition strategy and also provides synergy with our DOR technology providing the antibody for our ADC program.

- ***Parallel development of differentiated drug product candidates within a therapeutic strategic focus on diseases with unmet medical needs like blood related cancers***. We believe a development program leveraging distinct technologies across a pipeline of differentiated drug candidates offers an efficient model of how small biotech companies can align capital and clinical development execution while managing technology and regulatory risks. We will continue to be opportunistic in acquiring drug candidates that are within our therapeutic strategic focus, like our recent acquisition of TBS-2025. In addition to providing a Phase 2 ready candidate to advance to clinical studies in *mut*NPM1 AML, we are investigating TBS-2025 when conjugated to a DOR inhibitor as our lead ADC candidate in preclinical development.

- ***Establish a leadership position in developing immune modulating bi-functional, bi-specific ADCs.*** We believe that we may be the first company to identify that the Delta Opioid Receptor is highly expressed on tumor-associated MDSCs and that it controls the regulation of multiple immune suppressive functions of MDSCs, the primary contributor to immune suppression of the bone marrow in the tumor microenvironment. We believe that inhibiting MDSC functionality may represent a novel way to overcome acquired resistance to immunotherapies. Our immune modulating bi-specific, bi-functional ADCs represent a paradigm shift in this important class of therapeutics and have the potential to position TuHURA to take the lead on advancing these novel immunomodulatory bi- specific, bi-functional ADCs to clinical trials.

- ***Establish Development and Commercial License Collaborations***. Leveraging our CEO's track record of successfully establishing development and commercial partnerships, we intend to seek and establish partnerships with large pharmaceutical or biotech companies as a source of non-dilutive capital and funding to advance the global development of our product candidates.

Cancer Immunotherapies and IFx Technology

The Cancer-Immunity Cycle

For an anti-cancer immune response to lead to effective killing of cancer cells, a series of stepwise events must be initiated and allowed to proceed and expand iteratively. These steps are referred to as the "cancer-immunity cycle". The human immune system is comprised of the innate immune system and adaptive immune system. The innate immune response, through evolution, has developed to protect us from our surrounding environment. It is the defense system with which we are born and serves as the body's first defense mechanism against pathogens like bacteria or viruses and alerts the immune system to those threats. It works together with its complementary arm, the adaptive immune system, to address threats in the body, including cancer.

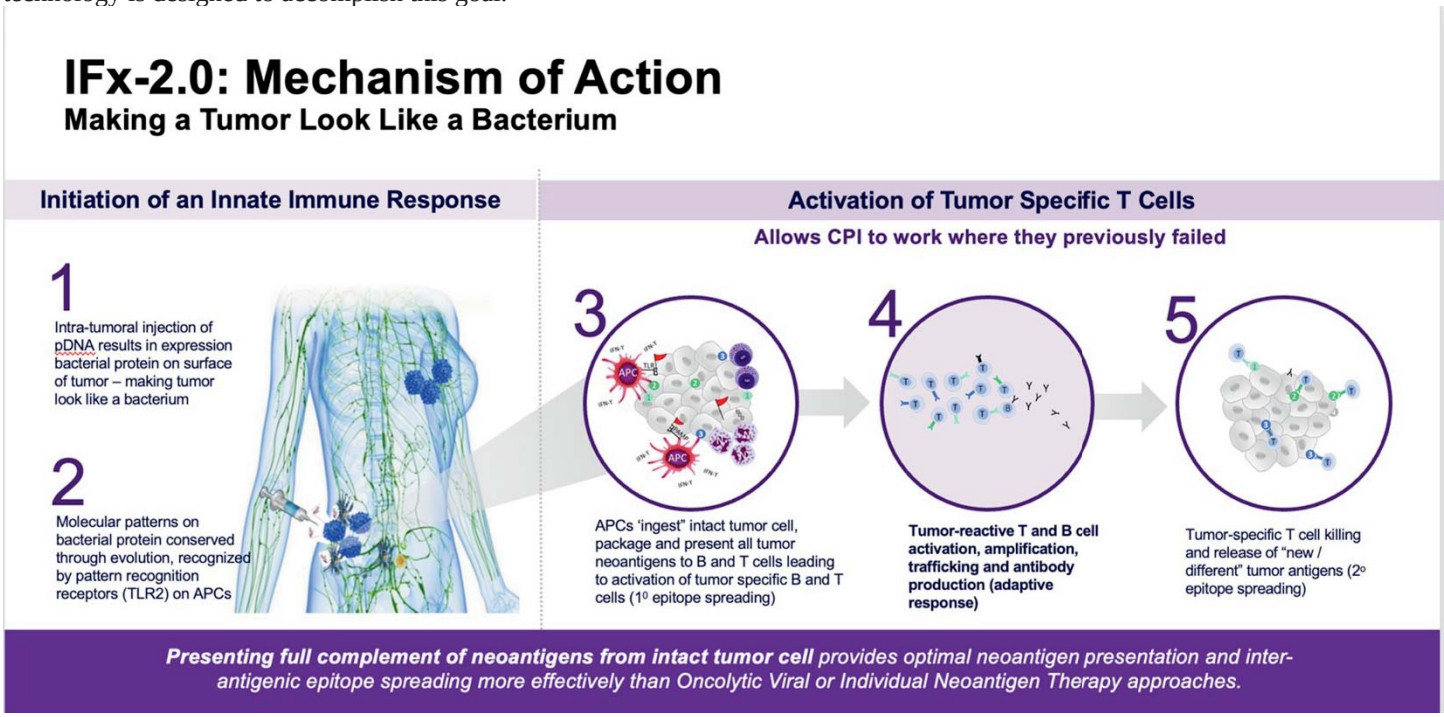
In the first step of the cycle, foreign proteins called "neoantigens" are created by cancer-related genes and are released and captured by dendritic cells ("DCs") for processing. In order for this step to lead to a tumor killing T cell response, it must be accompanied by signals that specify immunity, or otherwise tolerance to the tumor antigens will be induced. Such immunogenic signals might include proinflammatory cytokines and factors released by dying tumor cells. During the next step, DCs present the captured neoantigens on MHCI and MHCII molecules to T cells, resulting in the priming and activation of tumor cell killing, or cytotoxic, T cell responses against these cancer-specific neoantigens, which are viewed as foreign. Finally, the activated cytotoxic T cells traffic to and infiltrate the tumor bed, specifically recognizing and binding to cancer cells through the interaction between its T cell receptor and its cognate antigen bound to MHCI and kill their target cancer cell. Killing of the cancer cell releases additional tumor-associated neoantigens repeating the first step of the cancer- immunity cycle, to increase the breadth and depth of the response in subsequent revolutions of the cycle.

In cancer patients, the cancer-immunity cycle does not perform optimally. In order for an innate response to be activated against a tumor, the tumor must appear foreign to the immune system. Tumor neoantigens may not be detected due to low neoantigen load or mutational burden, DCs and T cells may treat antigens as self rather than foreign thereby creating T regulatory cell responses rather than cytotoxic responses, T cells may not properly home to tumors, may be inhibited from infiltrating the tumor, or, importantly, factors in the tumor microenvironment might suppress those effector T cells that are produced. The goal of cancer immunotherapy is to initiate and reinitiate a self-sustaining cycle of cancer immunity, enabling it to amplify and propagate.

IFx Technology

The goal of cancer immunotherapies generally is to initiate an immune response to tumor neoantigens, which are the abnormal proteins that tumor-associated genetic mutations cause the cells to produce. There are a number of approaches that attempt to make a tumor look foreign to the immune system. The optimal cancer immunotherapy would make a patient's entire tumor appear foreign and activate an innate immune response through the comprehensive and efficient packaging of tumor neoantigens which are

presented to cytotoxic T cells, leading to their priming, activation, and proliferation of an immune attack against the tumor. Our IFx technology is designed to accomplish this goal.



TuHURA's IFx platform technology utilizes a proprietary plasmid DNA (“pDNA”) or messenger RNA (“mRNA”) which, when introduced into a tumor cell, results in the expression of a highly immunogenic gram positive bacterial protein (Emm55) from a rare variant of Streptococcus pyogenes on the surface of the tumor cell. This is graphically demonstrated above. By mimicking a bacterium, our technology makes a tumor cell look like bacteria. By making a tumor look like a bacterium, the molecular pattern of the bacterial protein is recognized by specific receptors on immune cells called pattern recognition receptors, also referred to as toll-like receptors or TLRs. These receptors are pre-programmed over evolution to recognize specific molecular patterns or motifs on pathogens like bacteria and activate and harness the power of the body’s innate immune response.

IFx is designed to harness the body’s natural innate immune response making the patients entire tumor appear foreign. This causes antigen presenting cells (APCs) like DCs to phagocytize (which is the process of “eating” and “digesting”) the tumor cell, thinking they are bacteria. DCs present the captured neoantigens on MHCI and MHCII molecules to T cells, resulting in the priming and activation of cytotoxic T cell responses against these cancer-specific neoantigens, which are viewed as foreign. This is referred to as “primary epitope spreading.” Epitopes are the region/part of tumor antigens that are recognized by the immune system, specifically by antibodies, B cells and T cells. In doing so the first step of the cancer-immunity cycle is activated and restored.

Plasmid DNA, or plasmids, are small, circular, double-stranded DNA molecules that are separate from a cell’s chromosomal DNA and can replicate independently. Plasmids are most commonly found in bacteria, but can also be found in archaea and eukaryotic organisms. They can range in length from about 1,000 to hundreds of thousands of DNA base pairs. Plasmids often carry genes that can benefit the survival of an organism, such as antibiotic resistance. When a bacterium divides, all of the plasmids in the call are copied, so each daughter cell receives a copy of each plasmid. Plasmids can also be transmitted horizontally to other bacteria in some cases. Scientists have taken advantage of plasmids to use them as tools to clone, transfer, and manipulate genes.

Other Types of Cancer Immunotherapies

To date, most cancer immunotherapies, such as those described below, have utilized a number of different approaches to initiate an innate immune response to generate tumor specific activated T cells.

Oncolytic Virus Vaccines. Oncolytic virus vaccines are designed to preferentially induce viral replication-dependent oncolysis (viral induced killing) in tumors in an effort to stimulate antitumor immune responses. Intratumoral injection is thought to trigger both local and systemic immunological responses leading to tumor cell lysis, the release of tumor-associated antigens into the

tumor microenvironment where they need to be recognized by antigen presenting cells leading to subsequent activation of innate and adaptive immune systems to induce tumor antigen-specific effector T-cell antitumor immunity.

Tumor-associated antigen vaccines. Another approach is to utilize Tumor-Associated Antigens ("TAAs"), some of which may also be similar to self-antigens, although preferentially overexpressed on tumor cells. However, these TAAs may also be displayed by normal healthy cells or cancer testis antigens that are only expressed by tumor cells and adult reproductive tissues. T and B cells with high affinity toward these TAAs also target self-antigens leading to the removal of these T and B cells from the immune repertoire by central and peripheral tolerance. Thus, a potent vaccine must break tolerance for them to work. To date, this approach has had limited success.

Individual Neoantigen Therapy. Tumor-Specific Antigens ("TSAs") differ from tumor-associated antigens since they are not shared with similar self-antigens. They are typically de novo epitopes expressed by cancer-causing viruses (or oncoviruses) or private neoantigens encoded by somatic mutations. TSAs are truly tumor specific with no central tolerance. Deciding which TSAs to select and how to configure such multivalent vaccines is itself a daunting challenge. It may be insufficient to rely entirely on sequencing the expressed tumor genome looking for point mutations, translocation fusions, or CT antigens. Not only might this vary from patient to patient or even from cell to cell within a single patient's tumor, expression at the messenger RNA or protein level does not assure that predicted antigenic peptides will be generated and expressed as peptide-MHCI complexes, especially in the face of the allelic complexity in the MHC. Several groups are actively approaching this problem by using a combination of informatics and mass spectroscopy of peptides eluted from MHCI molecules. Early clinical trials used as neo-adjuvant therapy in combination with checkpoint inhibitors among patients with potentially surgically curable disease at risk for relapse has yielded encouraging results, although how best to deliver them to patients remains a critical unknown.

Potential Advantages of IFx Innate Immune Agonist Technology

IFx's approach is designed to naturally harness the power of the innate immune response leveraging Pathogen Associated Molecular Patterns (PAMP), or motifs present on pathogens, like bacteria and conserved through evolution. These patterns are recognized by pattern recognition receptors on antigen presenting and other immune cells of our innate immune system. By expressing a bacterial protein on the surface of a tumor cell the intact tumor cell is digested and the full complement of foreign tumor neoantigens are packaged and presented to newly produced T and B cells producing activated tumor specific T cells, the primary target allowing checkpoint inhibitors to work where they previously failed.

We believe that our IFx technology avoids problems associated with trying to predict which tumor- specific antigens are important and avoids the challenges associated with selection, analysis, production and delivery that accompanies individual neoantigen therapy approaches. Unlike oncolytic viral therapies which lyse the tumor cell disseminating tumor neoantigens throughout the tissue surrounding the tumor relying on antigen presenting cells in the vicinity to recognize, digest and present neoantigens to naïve T and B cells, IFx technology presents the full complement of tumor neoantigens from the intact tumor cell providing more optimal neoantigen presentation and inter-antigenic epitope spreading more effectively than oncolytic viral therapy or individual neoantigen therapy approaches.

Importantly, IFx is not an oncolytic viral technology. Oncolytic viral technologies which work by "exploding" the tumor cell resulting in the random dissemination of tumor neoantigens into the tumor microenvironment where immune cells can potentially see and digest them. In contrast, IFx presents the full complement of tumor neoantigens packaged inside the intact tumor cell providing much more optimal neoantigen presentation and more efficient inter-antigenic epitope spreading.

Clinical Rationale for TBS-2025

TBS-2025 (f/k/a KVA-12123), a VISTA inhibiting antibody, was initially investigated by Kineta in a Phase 1 trial either as monotherapy (n=24) or in combination with pembrolizumab (n=16) among patients with advanced, therapy refractory cancers, including, breast, lung, colorectal and ovarian cancer. The drug demonstrated a favorable safety profile at the highest dose level of 1,000mg administered every two weeks. No significant anti-tumor activity was observed among the 40 patients treated in the trial.

VISTA is a novel negative checkpoint expressed on quiescent (resting) T cells and highly expressed on myeloid cells like MDSCs. While VISTA is expressed on a wide variety of solid tumor cancers, its role in resistance or failure of cancer-immunotherapy is not well established. In contrast scientific evidence demonstrates that *mut*NPM1 a mutation present in approximately 30% to 35% of cases of AML, drives the expression of VISTA on leukemic blasts in AML and is reported to be the primary mechanism by which AML has a poor response to and high relapse rates following current therapies. VISTA expression is linked to high relapse rate in AML due to its ability to allow leukemic blasts to evade immune recognition and attack by the patient's

immune system. When VSIR, the gene that encodes for VISTA is edited or when VISTA is inhibited with a VISTA inhibiting antibody, an immune response is observed and survival is enhanced in murine models of *mut*NPM1 AML.

Recently, several new drugs called menin inhibitors have received approval in patients with relapsed and refractory (r/r) *mut*NPM1 AML. Menin is the "carrier" protein that exerts the proliferative effect on leukemic blasts. While the response rates of 22% to 25% that are seen following therapy with menin inhibitors are encouraging, they are of short duration followed by leukemia recurrence. For the >75% of patients who fail to respond to or relapse following a menin inhibitor, there are no approved or effective therapies. Translational scientific data supports the potential for TBS-2025 as monotherapy to improve potential response rates in this patient population.

Applying the FDA's guidelines for development of drugs in AML to the pharmacokinetic and safety data from VISTA 101, the Phase 1 study in solid tumors can potentially be used to determine a starting dose in a Phase 1b trial. We anticipate conducting an abbreviated Phase1b dose escalation study in *mut*NPM1 r/r AML in patients who failed to respond to or relapsed following therapy with a menin inhibitor in *mut*NPM1 r/r AML. This patient population represents an unmet medical need. We believe this population of patients with this genetic mutation may qualify for investigation under the FDA's Plausible Mechanism Pathway, which is a regulatory framework allowing approval based on biological rationale and target engagement rather than traditional, large randomized trials.

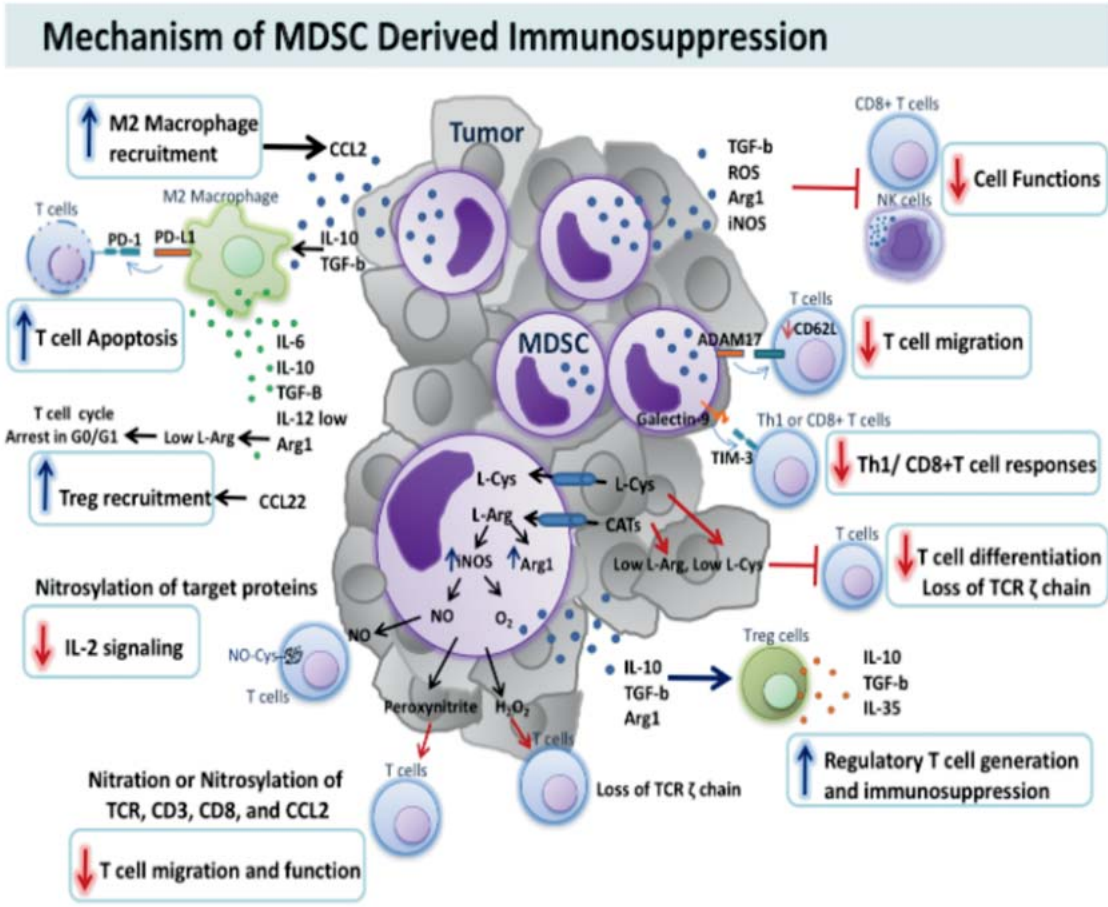
In addition to examining the potential of TBS-2025 monotherapy in this patient population, the Phase 1b study will also be used to establish a recommended dose to be investigated in a Phase 2 trial of TBS-2025 in combination with a menin inhibitor in *mut*NPM1 r/rAML in patients previously untreated with a menin inhibitor. The Phase 2 study would explore whether TBS-2025 when used in patients with *mut*NPM1 r/rAML who are receiving a menin inhibitor may improve both response rate and duration of response by allowing immune recognition and attack against leukemic cells. The Company plans on discussing its development plans with the FDA late in the first half of 2026 and initiating the planned Phase1b/2 trial in as early as the second half 2026.

DOR Technology and Bi-functional, Bi-specific ADCs: Inhibiting MDSC immune suppressing functions

MDSCs

MDSCs are among the most common immunosuppressive cells present in the bone marrow of patients with hematologic cancer and in the tumor microenvironment, which is the tissue surrounding the tumor, where they are a major regulator of suppression of the immune system. MDSCs are normally produced during pregnancy where they migrate to and populate the placenta, creating an immunologic sanctuary for the fetus. Since half of the genetic make-up of the fetus comes from the father, this is necessary to prevent the mother's immune system from attacking the fetus. They are also produced in settings of chronic inflammation or autoimmune disease as a mechanism to decrease inflammation or autoimmunity. Under normal conditions, MDSCs represent less than 2% of circulating peripheral blood mononuclear cells (PBMCs) and lack potent immune suppressing characteristics

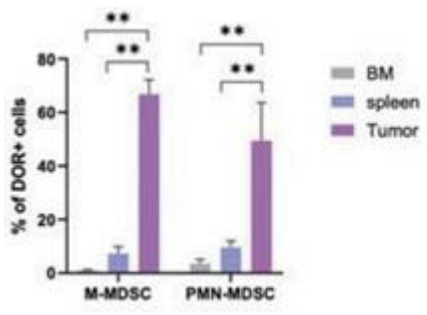
In cancer, MDSCs are hijacked by tumors to create an immunosuppressive environment in the tissues in which the tumor lives. In solid tumors, MDSCs are the primary driver of the immunosuppressive tumor microenvironment and function similarly in the bone marrow of patients with hematologic cancers like leukemia and MDS. Multiple effector molecules and signaling pathways are used by MDSCs to regulate immune suppression. One main mechanism involves depletion of necessary amino acids like arginine through production of arginase ("Arg-1"), or "destruction" of inflammatory cytokines via production of inducible nitric oxide ("iNOS"), in addition to anti-inflammatory prostaglandins ("COX2"), immune suppressing cytokines like transforming growth factor beta ("TGF-®") or Interleukin 10 ("IL-10") and recruitment and induction of immune inhibitory cells such as regulatory T cells (T regs) and M2 polarized tumor associated macrophages ("TAMs"). Accumulating evidence demonstrates that the enrichment and activation of MDSCs correlates with tumor progression, metastasis and recurrence. In addition, MDSCs circulating in the blood of patients with leukemia is highly correlated to poor clinical outcome.

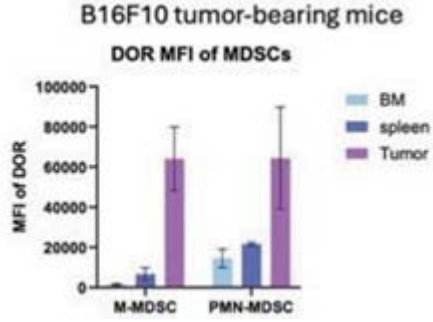


We believe that inhibiting and reprograming MDSC function represents a promising novel approach to overcome MDSC-induced tumor microenvironment immunosuppression and the resulting acquired resistance to cancer immunotherapies. Various companies are focusing on several strategies, including blocking MDSC recruitment to the microenvironment or inhibiting their production in the bone marrow. Another potential strategy is inhibiting MDSC-mediated immunosuppression by developing inhibitors to individual MDSC- related immune suppressing compounds such as IDO, iNOS or COX2 inhibitors.

Our Delta Opioid Receptor (DOR) inhibitors: bi-specific, bi-functional antibody drug conjugates (ADCs)

The Delta Opioid Receptor, or DOR, is the first cloned G protein-coupled receptor. While Delta Opioid Receptor overexpression and its role in tumor biology is well established in the literature, we believe that the Company, along with scientists at Moffitt Cancer Center, are the first to describe the high differential expression of the Delta Opioid Receptor on tumor associated MDSCs compared to bone marrow (BM) or spleen derived MDSCs, either in tumor free or tumor bearing models. (See figures below, source: TuHURA research files).





MDSC: MDSC isolated from BM, spleen and Tumor. * p α 0.05, ** p α 0.01

As a previously unrecognized target to reprogram tumor associated MDSCs immunosuppressive functions on the tumor microenvironment, developing small molecule antagonists of the Delta Opioid Receptor represents a novel approach to reprograming MDSC functionality to overcome acquired resistance to checkpoint inhibitors and other cancer immunotherapies.

The Company has established multiple functional assay screens to investigate the effects of small molecule Delta Opioid Receptor specific inhibitors of tumor-associated MDSC functionality to guide its selection of ADCs for further *invitro* and *in vivo* characterization and development. The Company anticipates utilizing TBS-2025, its VISTA inhibiting antibody, as the first ADC to enter preclinical development.

The Company believes that our tumor associated MDSC-targeting ADCs have a number of potential benefits over current approaches to overcoming acquired resistance to cancer immunotherapies, including the following:

- **Inhibiting tumor associated MDSC production of multiple immune suppressing factors**. The Delta Opioid Receptor on tumor associated MDSCs functions like a "master switch" controlling the regulation of multiple immune suppressing factors such as, iNOS, S100A9 among others. Inhibiting the receptor results in "shutting off" production of these and other immune suppressing factors as compared to the industry focus of developing inhibitors targeting a single factor.

- **Blocking tumor associated MDSC recruitment to the microenvironment.** To exhibit their immunosuppressive phenotype, MDSCs have to be recruited to the tumor site, transitioning to tumor associated MDSCs which display maximum immunosupressive properties. This process is mediated mainly by chemokines secreted in the tumor microenvironment and chemokine receptors expressed on MDSCs. There are a number of strategies to prevent the recruitment of MDSCs to the microenvironment through the development of inhibitors of chemokines such as CCL2/CCR2 blockade. However brain, heart, kidney, liver, lung, ovary, pancreas, spinal cord, spleen, and thymus also express CCR2, introducing the potential for off-target side effects with this approach. Inhibiting the Delta Opioid Receptor prevents the proliferation and production of tumor associated MDSC-monocyte subpopulations (M-MDSC), promotes repolarizing M2 to M1 phenotype decreasing Th-2 cytokines while increasing Th-1 (g-IFN, IL-2) cytokines. Thus changing the immunosuppressive phenotype of the tumor microenviroment to an immunogenic phenotype more favorable to cancer immunotherapies.

- **Immune modulation of tumor microenviroment/potentiating the effects of checkpoint inhibitors.** To date the prior and future development of ADC,s ADC-checkpoint inhibitors or bi-specific all have one thing in common, which is that they target tumor associated receptors with the antibody and carry with it either a payload toxin, or other tumor cell cycle disruptors or checkpoint inhibitor. To our knowledge we are the only company developing ADCs targeting MDSCs where our ADCs are designed to be bi-specific/ bi-functional, *i.e.*, affecting two targets and having two functions: inhibiting tumor associated MDSC-related immune suppression and thereby making tumor susceptible to attack, while localizing checkpoint inhibitors where the tumor resides. These two functions are intended to work together with the goal of overcoming acquired resistance, preventing T cell exhaustion and allowing checkpoint inhibitors and cellular therapies to be safer and more effective while interfering with the tumor's ability to invade and spread throughout the body.

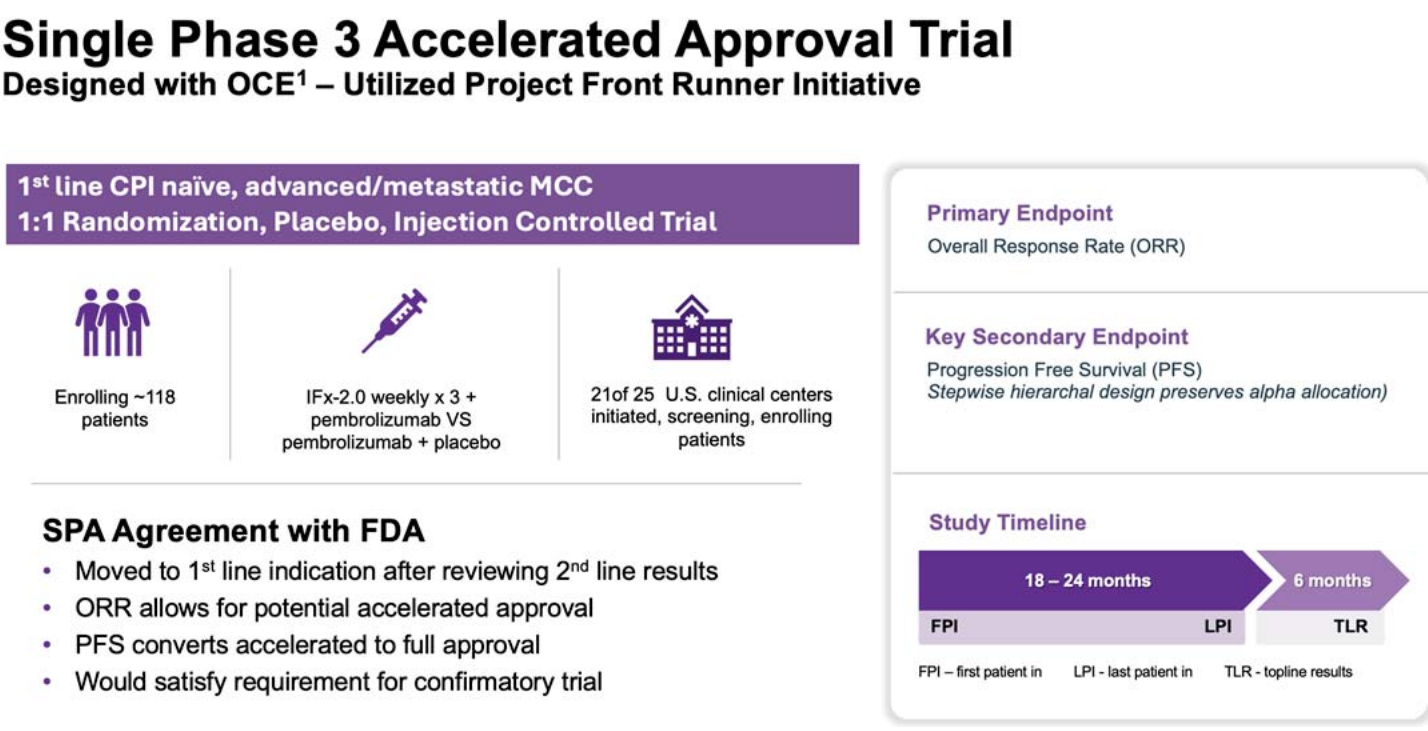
TuHURA's IFx Clinical Development Program

For purposes of the below descriptions of our Phase 1 and 1b clinical trials, the response rates for IFx-2.0 are determined under best clinical practice by the principal investigators, evaluating and confirming clinical progression prior to or during therapy utilizing conventional and appropriate radiographic or metabolic (Positron Emission Tomography – PET) methodologies. Response determination utilizes conventional terminologies under standardized response evaluation criteria. A "complete response", or CR, is deemed to be disappearance of all lesions. A "partial response", or PR, is at least a 30% decrease in the sum of the size of the target lesions. "Progressive disease", or PD, is at least a 20% increase in the sum of the longest diameter or the appearance of new lesions. "Stable disease", or SD, means that the patient has neither sufficient shrinkage in the lesions to qualify for PR nor sufficient increase to qualify for PD. The term "objective response rate" is defined as the proportion of patients who have a partial or complete response to therapy. Furthermore, the term "pCR" refers to a pathological complete response, which is the absence of signs of cancer in tissue samples removed during surgery or biopsy after treatment. "Progression-free survival", or PFS, means the length of time after the treatment that a patient lives without disease progression.

Accelerated Approval Phase 3 Trial for IFx-2.0

TuHURA has entered into a Special Protocol Assessment agreement with the FDA for a single Phase 3 randomized placebo and injection controlled trial for IFx-2.0, its lead innate immune agonist, as adjunctive therapy to pembrolizumab (Keytruda®) in the first line treatment of patients with advanced or metastatic Merkel cell carcinoma, who are checkpoint inhibitor-naïve utilizing the FDA's accelerated approval pathway. The Company has worked the deputy director of the FDA's Oncology Center of Excellence (OCE) on a unique trial design. Consistent with the FDA's Project Front Runner initiative, the FDA recommended the Company consider investigating IFx-2.0 in the front line treatment setting rather than in patients who are progressing on checkpoint inhibitor therapy, the latter of which was the conduct in the phase 1b trial. In doing so, data from a primary endpoint of objective response rate, or ORR, that is of sufficient magnitude and duration and with a favorable risk/benefit profile could be sufficient to support accelerated approval. ORR is considered to be a surrogate likely to predict clinical benefit, OCE requested that the Company also consider incorporating a key secondary endpoint that is not a surrogate for but an endpoint recognized to be of true clinical benefit such that results from a key secondary endpoint of progression-free survival, or PFS, that is adequately powered with statistical assumptions in the statistical analysis plan provided to the FDA, if achieved without a detrimental effect on overall survival, or OS, could be adequate to support conversion to regular approval satisfying the requirement for a confirmatory trial.

TuHURA anticipates that enrollment for the Phase 3 will take approximately 18 – 24 months, with topline data potentially being available 6 to 7 months following the last patient enrolled. If successful, this Phase 3 trial would form the basis of a Biologics License Application, or BLA. A Special Protocol Assessment agreement is a binding written agreement between the U.S. Food and Drug Administration (FDA) and a trial sponsor that indicates the FDA has agreed to the study's design, charters, and statistical analysis plan and if the study endpoints are met within the context of the SPA Agreement such results would be adequate to support accelerated and regular approval. A Special Protocol Assessment agreement does not increase the likelihood of marketing approval for the product and may not lead to a faster or less costly development, review, or approval process. The study population, dose, schedule, and study design for the trial are based on the response rates observed in the Company's Phase 1b trial in checkpoint inhibitor naïve patients with advanced Merkel cell carcinoma who exhibited primary resistance to anti PD(L)-1 checkpoint inhibitors such as Keytruda® The clinical study design for the Phase 3 registration trial is presented below. Based on correspondence with the FDA, patients with advanced Merkel cell carcinoma represent a patient population with an unmet medical need. TuHURA's study, is designed to determine if IFx-2.0 can increase the objective response rate when used as adjunctive therapy to Keytruda in first line treatment of checkpoint inhibitor naïve patients with advanced Merkel cell carcinoma when compared to Keytruda alone.



Note: "FPI" means first patient in, "LPI" means last patient in, and "TLR" means top-line results. Progression Free Survival, or PFS, is defined as the time from randomization until first evidence of disease progression or death, and Overall Survival, or OS, is defined as the time between randomization to death.

Phase 1b Trial in Metastatic Merkel Cell Carcinoma and Cutaneous Squamous Cell Carcinoma

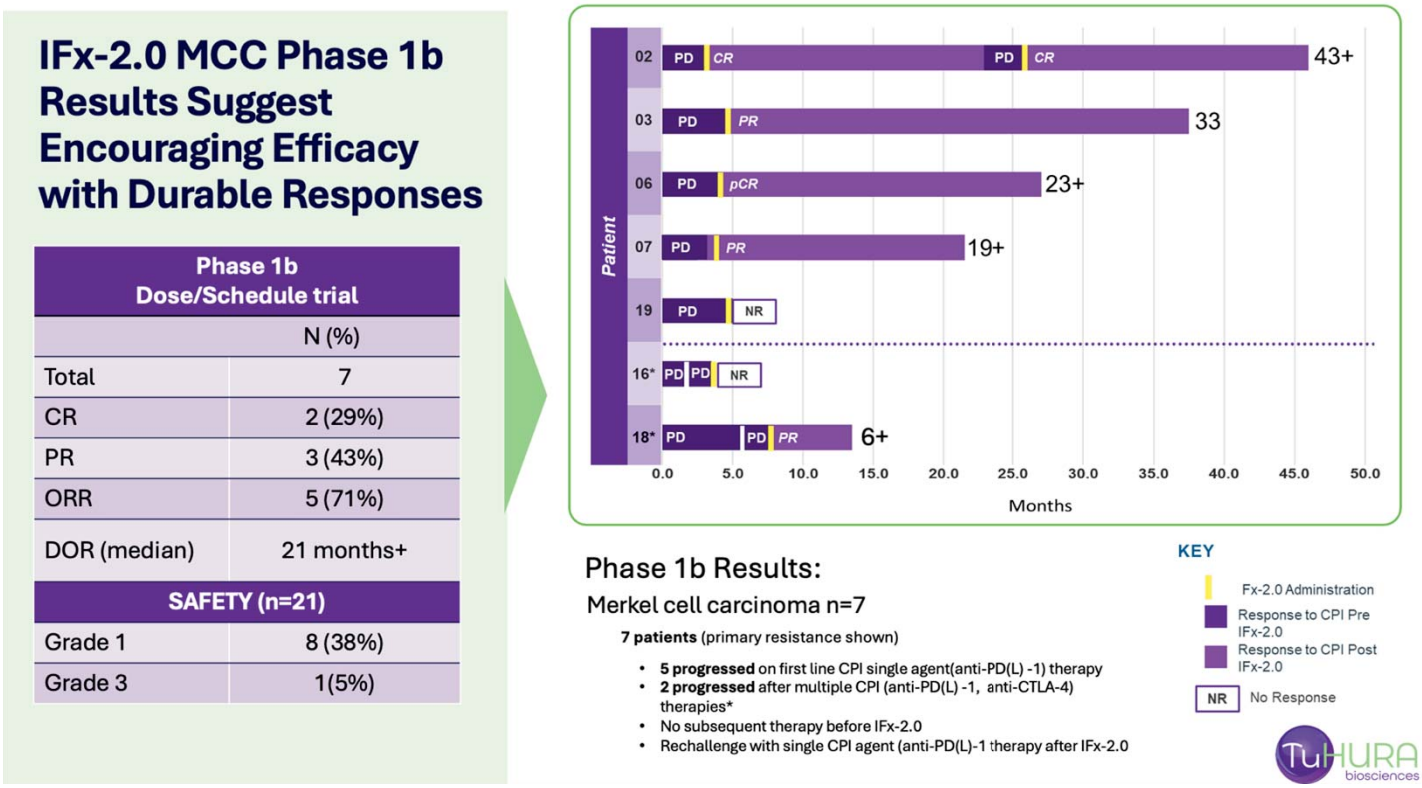
We have completed enrollment in a multicenter Phase 1b dose and schedule finding trial for our IFx-Hu2.0 innate immune agonist candidate in patients with advanced Merkel cell carcinoma (MMC) or cutaneous Squamous cell carcinoma (cSCC). This study follows a two-stage design with a primary goal to assess the safety and feasibility of repeated dosing schemas of IFx-2.0. In the first stage (exposure escalation), a 3+3 trial design was utilized to assess safety of repeated weekly intratumoral injections using a fixed dose of IFx-2.0 weekly for 1, 2 or 3 weeks (for cohorts 1, 2 or 3 respectively). Following safety evaluation the protocol was amended to include an expansion stage to increase the total study sample size to 20. A total of 23 patients were enrolled. As of June 2024, follow-up data was available on all evaluable patients.

The primary objective of the trial was to determine the safety, tolerability, and optimal dose and schedule of IFx-2.0 when administered intratumoral in up to three lesions injected across three different administration schedules. Safety was evaluated for up to 28 days following IFx-2.0 administration. Secondary objectives include tumor shrinkage (injected and non-injected lesions) and correlative immune response analysis (transcriptomic, proteomic, humoral and cellular), pre-and post-IFx-2.0 administration to guide the choice of dose and schedule for our Phase 3 registration directed trial.

Twenty-three (23) patients were enrolled: Merkel cell carcinoma (13), cSCC (10). Among the thirteen (13) patients with Merkel cell carcinoma, twelve (12) completed treatment and the protocol directed 28 day safety evaluation follow up period; One (1) patient experienced a serious adverse event, or SAE, deemed possibly related to study drug. This patient experienced a Grade 3, or G3, adverse event, which is defined as an adverse event that is a severe or medically significant event that is not immediately life threatening, which in the case of this patient was a G3 autoimmune hepatitis that resolved with steroid treatment, and such patent has been recently treated with checkpoint inhibitors prior to study enrollment. Among the ten (10) patients with cSCC one (1) patient experienced an SAE unrelated to study drug and did not complete treatment nor the 28 day safety evaluation follow up period. All patients had received prior anti-PD(L)1 based treatment with disease progression being the reason for CPI discontinuation in all patients but one. Intra- tumoral (IT) IFx-2.0 was well tolerated at all dose schedules evaluated. As to efficacy, in the 21 patients that completed the study, best overall disease response to trial therapy was PR in 1 patient (including both injected and non-injected tumor sites), SD in 4, and PD in 16. The response assessment limited to the injected site(s) only was PR in 2 patients, SD in 8, and PD in 9. Two additional patients were not evaluable at the injected site(s) due to clinically challenging to measure dermal lesions that were not radiographically measurable. The study achieved the primary safety endpoint of the study demonstrating no grade 3 or greater toxicity in any of the 3 dose levels examined, and as a result, a recommended phase 2 dose was determined. The study also achieved its secondary endpoint of efficacy analysis demonstrating a disease control rate of 48% among injected lesions within the first 28 days post injection, and, as described below, a post-protocol efficacy analysis demonstrated an overall objective response rate of 64% (7 of 11 patients with Merkel cell carcinoma) after re-challenge with immune checkpoint inhibitors.

After protocol specified IT therapy, eleven (11) Merkel cell carcinoma patients and six (6) cSCC pts were treated with anti-PD(L)1 based therapy as the immediate post-protocol treatment. Five (5) of nine (9) (56%) evaluable Merkel cell carcinoma patients and one (1) of (6) (17%) cSCC patients experienced an objective response to this ICI rechallenge, with duration of response ongoing in four (4) patients (6+, 19+, 21+, 23+ months) and the two other responses lasting 23 and 33 months. The two (2) remaining Merkel cell carcinoma patients were not evaluable for response from IO rechallenge due to radiation administered to the only measurable disease site(s), but both remain progression free at 11+ and 13+ months with previously progressive disease.

Of the twelve (12) patients with advanced Merkel cell carcinoma who completed treatment and protocol-directed 28-day safety evaluation follow-up period, seven patients exhibited primary resistance to first line treatment with a checkpoint inhibitor who did not receive subsequent therapies prior to receiving IFx-2.0. Five of seven patients received single agent anti-PD(L)-1 as initial therapy while two of seven patients received multiple CPIs as initial therapy including anti-PD-1, followed by anti-PD-1/anti-CTLA-4 therapy. All 7 patients exhibited primary resistance to checkpoint inhibitor therapy progressing on average 3.3 months while receiving CPI therapy. These 7 patients are graphically presented below:



This data demonstrating the potential for IFx-2.0 to overcome primary resistance to anti-PD(L)-1 therapy and formed the clinical rationale for examining IFx-2.0 as adjunctive therapy with Keytruda® (anti-PD-1) in first line therapy among checkpoint inhibitor naïve patients with advanced or metastatic Merkel cell carcinoma. Unlike the phase 1b where IFx-2.0 was administered after patients progressing on anti-PD(L)-1 therapy, we believe IFx-2.0 could potentially provide a higher response rate to Keytruda® when administered prior to patients progressing failing Keytruda®.

The remaining seven (7) patients received multiple checkpoint inhibitor therapy including anti- CTLA-4/anti-PD-1 therapy and/or investigational agent(s) and or chemotherapy as 2nd or 3rd line therapy prior to treatment with IFx-2.0. This patient population is not representative of patients to be enrolled in the phase 3 trial.

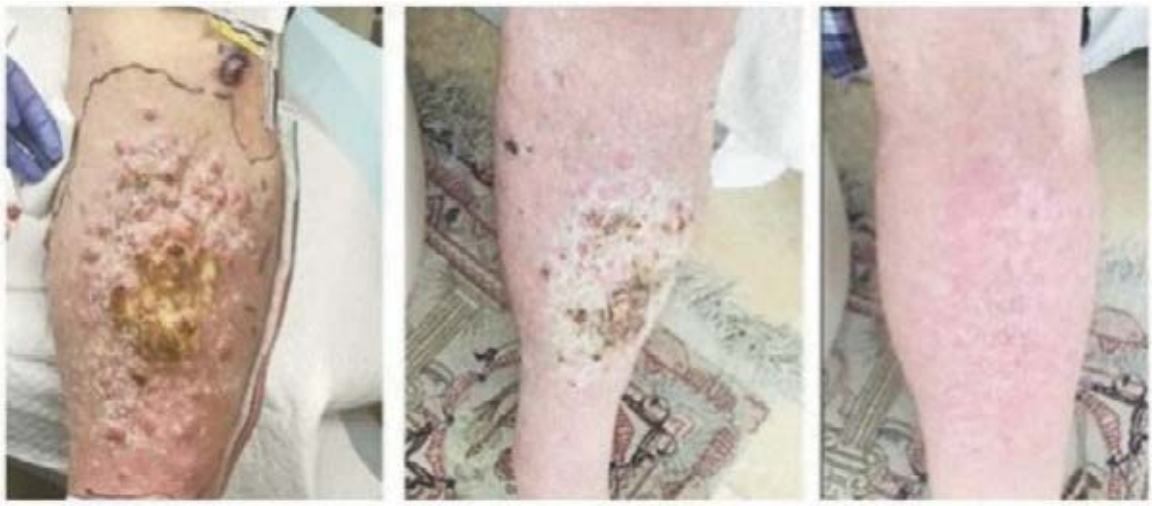
Importantly, IFx-2.0 is not an intratumoral therapy like oncolytic viral therapies whose anti-tumor activity is limited to accessible, injected lesions in limited stages of cancer. In contrast, IFx-2.0's mechanism of action is to prime and activate an innate immune response in injected lesions leading to a systemic anti-tumor response. The Company chose to examine IFx-2.0 in cutaneous malignancies because human skin has a high density of DCs which are very efficient in presenting foreign antigens to immune cells. Local injection of IFx-2.0 into cutaneous lesion(s) has resulted in immune cell infiltration, and in the context of MHCI and MHCII, tumor neoepitope presentation to naïve B and T cells followed by activation of tumor specific B and T cells. The immune response has not been localized to just injected lesions but rather systemic as demonstrated by production of Emm55 (pDNA encoded bacterial protein expressed on the surface of the tumor cell) and tumor specific IgM and IgG antibodies in the plasma of patients post IFx-2.0 administration.

Patients Merkel cell carcinoma-03 and Merkel cell carcinoma-05 below demonstrate the abscopal effect of adjunctive IFx-2.0 therapy, These patients exhibited primary resistance to checkpoint inhibitor therapy, and subsequently achieved durable anti- tumor responses following IFx-2.0 and rechallenge with checkpoint inhibitor therapy.

Case study (MCC-005)

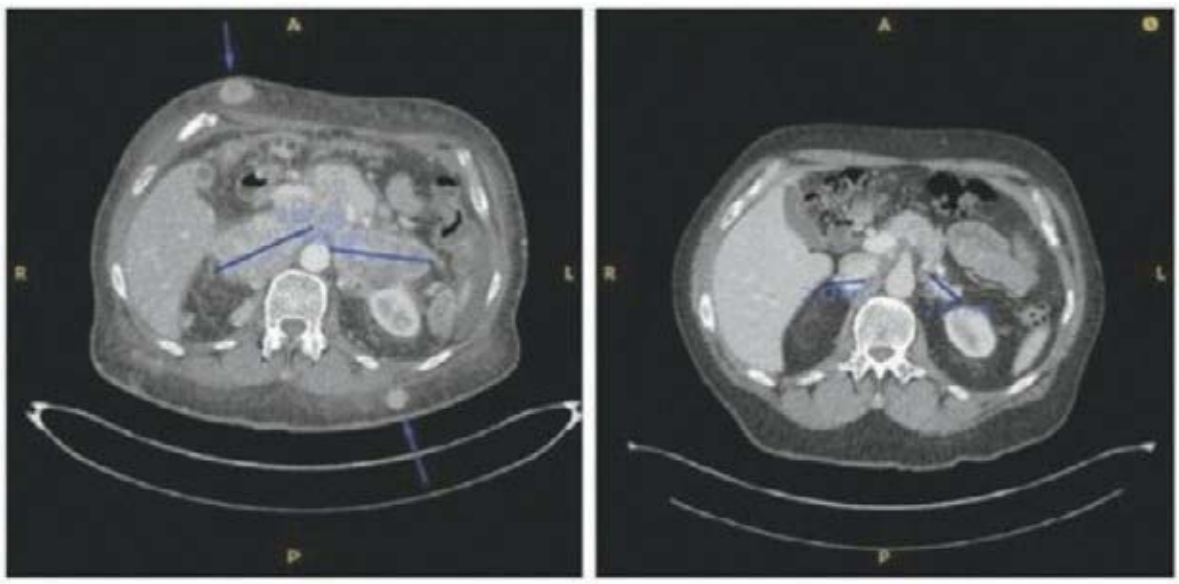
Patient was treated for multifocal in-transit recurrence of Merkel cell carcinoma in left leg with avelumab x 6 doses (12 weeks) with continued rapid clinical progression as well as development of liver metastatic disease on this therapy. Subsequently the patient was enrolled on IFx-2.0 protocol and received 3 weekly injections of IFx-2.0 without complication but continued clinical progression (additional in-transit sites). Disease status at time of last injection shown on the left. Following completion of IFx-2.0

protocol therapy, subject was rechallenged with pembrolizumab, a checkpoint inhibitor, and experienced an obvious clinical response initially apparent approximately 3-4 weeks into therapy. Clinical response at 3 months (middle photo below) and 6 months (right photo below) are shown in the photos below. Concordant (near-complete) radiographic response of liver metastases has also been observed and response has been maintained to date (19 months)



Case study (MCC-002)

Subject was treated with adjuvant pembrolizumab for stage II Merkel cell carcinoma on the STAMP trial but developed (nodal) progression after receiving 6 doses. Subject underwent salvage surgery/XRT but developed widespread metastatic disease ~3 months later (nodal, dermal, and intramuscular sites of disease). Subject was then enrolled on IFx-2.0 protocol and received 2 weekly injections to 3 nodal/dermal metastatic sites but experienced continued rapid progression (both injected and non-injected sites) including bulky diffuse adenopathy and numerous widespread subcutaneous/dermal nodules. Representative imaging from the time of completion of protocol therapy is shown on left in photo below including several subcutaneous sites (as noted by the arrows) and bulky retroperitoneal ("RP") conglomerate lymph node ("LN") metastases. Post-protocol, subject was started on checkpoint inhibitor rechallenge with avelumab and experienced deep partial response that has been maintained to date (33 months). Representative images from post-checkpoint rechallenge restaging shown below on right (complete remission of subcutaneous nodules, partial response in retroperitoneal sites).



In May 2025, we initiated a Phase 1b/2a trial designed to evaluate the safety and feasibility of IFx-Hu2.0 in combination with Keytruda® when administered via Interventional Radiology (IR) in patients with deep- seated tumors without associated cutaneous tumors. Unlike our Phase 3 study, these are patients without skin lesions who present with metastatic deep-seated tumors in the liver, lungs or retropertitoneum (abdomen). Up to 30% of patients with MCC present without primary lesions in the skin, so this trial will not only provide safety, feasibility, and efficacy data, but may also expand the potential number of addressable patients who may benefit from IFx-Hu2.0,

If feasibility and safety is demonstrated for IFx-Hu2.0 and Keytruda® when radiologically administered to deep-seated tumors, we plan to extend enrollment to a variety of non-MCC cancers that are known not to respond or respond poorly to CPIs. This is termed a "Basket Trial." Since the underlying biology of why tumors don't respond to CPIs is for the most part the same, then we believe that the mechanism of how IFx-Hu2.0 overcomes that resistance to CPIs should be independent of the type of cancer treated. We have previously demonstrated that IFx-Hu2.0 can overcome CPI resistance in melanoma, squamous cell, and Merkel cell carcinoma, three unrelated types of skin cancers. If successful, this trial could expand the potential benefit of IFx-Hu2.0 to a wide variety of cancers.

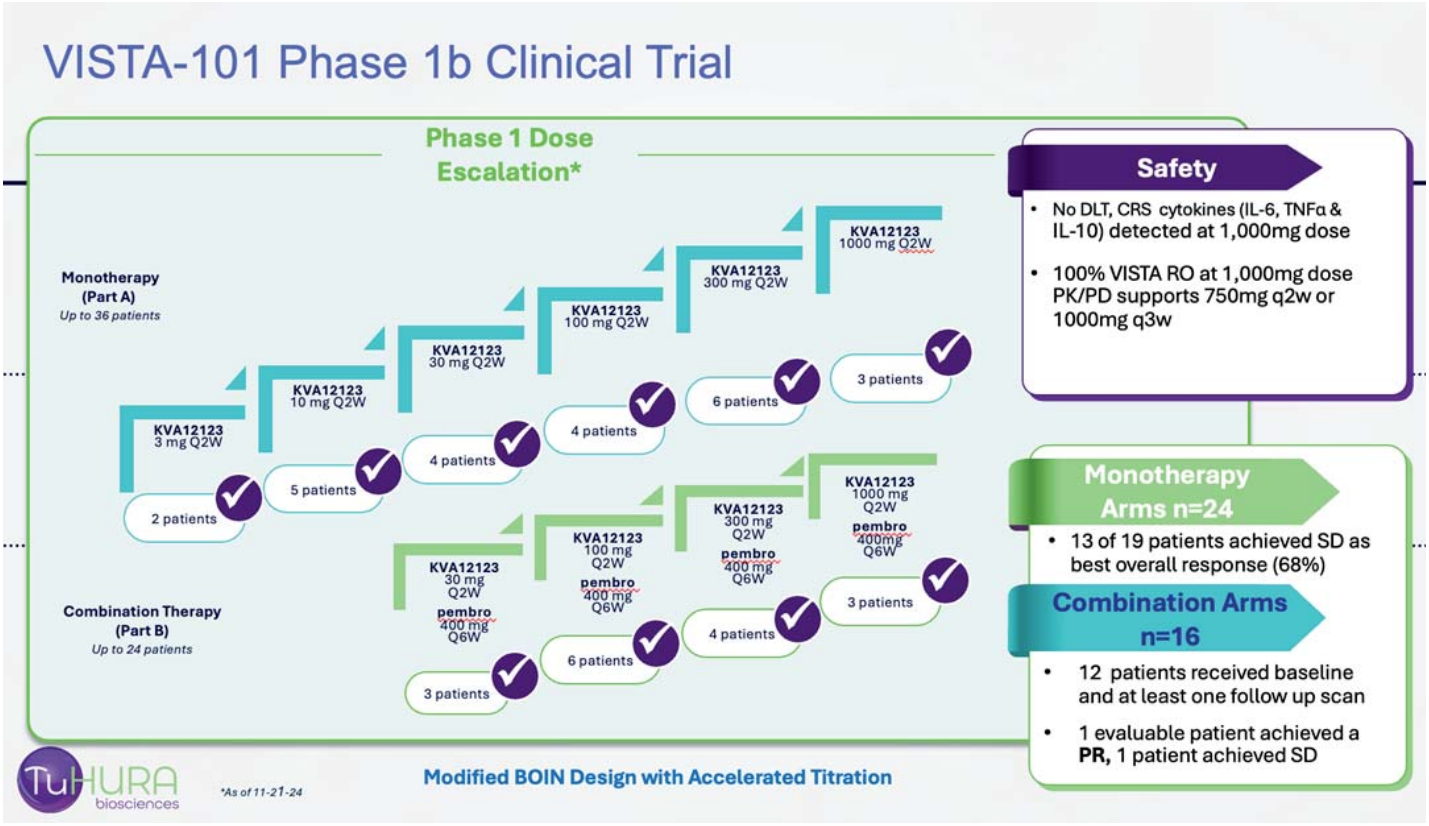
Phase 1 Trial in Advanced, (Stage IIIC-IV) Cutaneous Melanoma

We also conducted a Phase 1 trial at the Moffitt Cancer Center in seven (7) patients with advanced (Stage IIIc/IV) cutaneous melanoma, six (6) of whom were eligible for evaluation post-IFx-2.0 therapy. The primary objective of the trial was to determine the safety and tolerability of IFx-2.0 when administered intratumorally with up to three lesions injected at a single time point. Safety was evaluated for 28 days following IFx-2.0 administration. Secondary objectives included tumor shrinkage, transcriptomic, proteomic, humoral, and cellular immune response pre and post IFx-2.0 administration. IFx-2.0 was well tolerated. Mild pain and swelling among injected lesions were most common reported side effect < Grade 2 in severity. Four (4) of the six (6) patients exhibited primary resistance to, and failed checkpoint inhibitor trials prior to IFx-2.0. Following IFx-2.0 administration three (3) of four (4) patients subsequently responded to rechallenge with checkpoint inhibitor(s). One patient achieved stable disease ("SD") and 2 experienced a partial response ("PR"). As of the last follow up responses are ongoing at 1337, 608, 313 days. Two (2) patients (SD and PR) underwent surgical resections following checkpoint inhibitor therapy. Immunologic profiling data (pre-and post-IFx-2.0) demonstrated a robust systemic immune response with (i) activation of tumor specific B cells with tumor specific IgM/IgG antibody production recognizing hundreds of previously unrecognized melanoma tumor neoepitopes and (ii) gene signature, consistent with innate response in injected lesions, a gene signature consistent with adaptive response in un-injected lesions as well as increased expression (up to 11 fold) of genes known to be predictive of response to checkpoint inhibitors following IFx-2.0 therapy but prior to checkpoint inhibitor rechallenge.

TuHURA's TBS-2025 VISTA Inhibiting Antibody Clinical Development Program

TBS-2025 (f/k/a KVA-12123), a VISTA inhibiting antibody, was initially investigated by Kineta in a Phase 1 trial either as monotherapy (n=24) or in combination with pembrolizumab (n=16) among patients with advanced, therapy refractory cancers, including, breast, lung, colorectal and ovarian cancer. The Phase 1 was an open-label, multi-center, dose-escalation trial, utilizing an accelerated Bayesian Optimal Interval (BOIN) dosing design designed to evaluate the safety, tolerability, pharmacokinetics ("PK"), immunogenicity, and tumor response of TBS-2025. TBS-2025 demonstrated a favorable safety profile at the highest dose level of 1,000 mg administered every two weeks. In this trial among patients with treatment-refractory solid tumors, no significant anti-tumor activity was observed among the 40 patients treated in the trial.

An overview of the study results is shown below:



Clinical collaboration with Merck

Kineta previously entered into a clinical trial collaboration and supply agreement with Merck (known as MSD outside the U.S. and Canada) that we have assumed as a part of the Kineta acquisition. Under this collaboration, we are evaluating the safety, tolerability, PK. and anti-tumor activity of TBS-2025 alone and in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in patients with advanced solid tumors.

Pharmacokinetics (PK) and Receptor Occupancy (RO)

Pharmacokinetics, or PK, is the study of how the body interacts with TBS-2025 for the entire duration of exposure after administration. TBS-2025 exhibited a greater than dose-proportional pharmacokinetic profile in drug exposure across all doses, consistent with target-mediated drug disposition at lower doses and target saturation at higher doses.

To guide the recommended Phase 2 dose decision, Kineta developed a proprietary assay to evaluate VISTA receptor occupancy ("RO") on immune cells from patients treated with TBS-2025. This is an important metric for evaluating how well TBS-2025 is blocking the VISTA target. TBS-2025 achieved a greater than 90% VISTA RO at the 30 mg dose and a complete saturation of the target between two-dosing intervals was achieved at 1000 mg. Based on these data. the Company believes the Recommended Phase 2 Dose (RP2D) should be 750mg every two weeks.

Biomarkers

In drug development and clinical trials, biomarkers may be useful to identify patient populations for a study, monitor therapeutic response, and identify side effects. TBS-2025 demonstrated dose-proportional on-target biomarker immune responses involved in anti-tumor activity. TBS-2025 demonstrated significant efficacy- related, dose-dependent cytokine induction of CXCL10, IFNα, CCL2 (MCP1), CCL3 (MIP1α), CCL4 (MIP1ß) and CXCL8 (IL8), which are involved in immune cell activation and recruitment to the tumor microenvironment. Additionally, increases in anti-tumor immune cell subpopulations including nonclassical monocytes with an activated phenotype (increased of cell surface expression of HLA-DR and CD80), NK cells, CD4+ T cells and CD8+ T cells were observed during treatment.

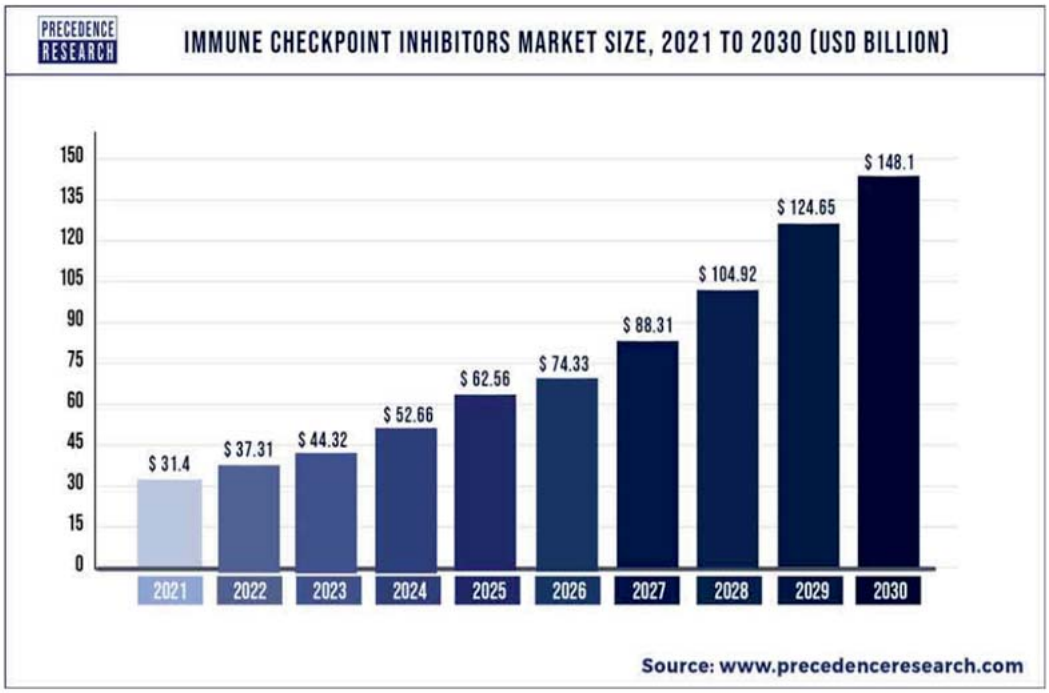
TBS-2025 demonstrated induction of pro-inflammatory myeloid-derived cytokines/chemokines involved in immune cell activation and recruitment in the tumor microenvironment. Changes in these key biomarkers and immune cell populations are indicative of the anti-tumor effects of blocking VISTA that is consistent with data from preclinical models (NHP and KO mice). These data validate their use as potential biomarker of VISTA target engagement with TBS-2025

Phase 1b/2 trial TBS-2025 in mutNPM1 r/r AML

Applying the FDA's guidelines for development of drugs in AML to the pharmacokinetic and safety data from VISTA 101, the Phase 1 study in solid tumors can potentially be used to determine a starting dose in a Phase 1b trial. We anticipate conducting an abbreviated Phase1b dose escalation study in mutNPM1 r/r AML in patients who failed to respond to or relapsed following therapy with a menin inhibitor in *mut*NPM1 r/r AML. This patient population represents an unmet medical need. We believe this population of patients with this genetic mutation may qualify for investigation under the FDA's Plausible Mechanism Pathway, which is a regulatory framework allowing approval based on biological rationale and target engagement rather than traditional, large randomized trials. In addition to examining the potential of TBS-2025 monotherapy in this patient population, the Phase 1b study will also be used to establish a recommended dose to be investigated in a Phase 2 trial of TBS-2025 in combination with a menin inhibitor in *mut*NPM1 r/rAML in patients previously untreated with a menin inhibitor. The Phase 2 study would explore whether TBS-2025, when used in patients with *mut*NPM1 r/rAML who are receiving a menin inhibitor, may improve both response rate and duration of response by allowing immune recognition and attack against leukemic cells. The Company plans on discussing its development plans with the FDA in the first half of 2026 and initiating the planned Phase1b/2 trial in as early as the second half 2026.

Market Opportunity

Checkpoint inhibitors dominate oncology sales and represent the most successful oncology drug commercial launches in oncology drug development. Since their commercial launch in 2014, sales of checkpoint inhibitors have grown at an impressive compounded annual growth rate with $29.9 billion in sales in 2020 reaching $37 billion in 2022, according to Precedence Research. By 2030 the market is expected to grow to over $148 billion in worldwide sales, according to Precedence Research. We believe that our technology platforms have the potential to address both primary and acquired resistance, the two major limitations to checkpoint inhibitor and cellular therapies and as such represents a large market opportunity. While upward of 15% to 60% of patients will respond to first time treatment with checkpoint inhibitors, 40% to 85% will not. It is this population of patients with primary resistance to checkpoint inhibitors that we believe represents the initial market opportunity for IFx-2.0. The biologic basis for primary resistance to checkpoint inhibitors is similar across various tumor types, predominately the lack of tumor infiltration with activated tumor specific T cells. We believe that an agent that can overcome primary resistance to checkpoint inhibitors in one tumor type should overcome resistance in others, if not all, tumor types that exhibit primary resistance to them. Our initial strategy is to demonstrate the ability of IFx-2.0 to overcome primary resistance in the 50% of patients with advanced Merkel cell carcinoma receiving front line therapy with Keytruda® (pembrolizumab), the current standard of care, allowing more patients to achieve an anti-tumor response than with Keytruda® alone.



According to DelveInsight, it is estimated by 2027 there will be approximately 4,245 patients in the US and 7,049 patients in the 7 major market European countries, including the UK, growing to a total of 15, 262 patients by 2034 in these geographic territories. The standard of care for patients with the advanced or metastatic Merkel cell carcinoma is therapy with a checkpoint inhibitor like Keytruda® (pembrolizumab). If the results of our above-described "basket" trial are successful, the results from that clinical trial could allow IFx-2.0 to be used in a variety of tumor types other than Merkel cell carcinoma that exhibit primary resistance to checkpoint inhibitors, which could expand the market application of IFx-2.0 significantly.

Among patients who initially respond to treatment with checkpoint inhibitors, almost all patients will ultimately develop acquired resistance where checkpoint inhibitors no longer work and the tumor recurs and/or progresses. While the cause of acquired resistance is multifactorial, a major contributor is tumor associated MDSC-induced immunosuppression of the tumor microenvironment leading to T cell exhaustion and failure of checkpoint inhibitors or cellular therapies. Our initial strategy is to investigate our MDSC-targeted bi-functional ADCs in tumor types that initially responded to and subsequently progressed on or following checkpoint inhibitor therapy. If successful in overcoming acquired resistance to checkpoint inhibitors while potentially limiting their toxicity to non-tumor tissue, such an application would be expected to also represent a significant market opportunity.

TuHURA's Manufacturing Strategy

TuHURA maintains established relationships with contract development and manufacturing organizations (CDMOs) to manufacture and test IFx-Hu2.0 clinical trial material ("CTM"), including drug substance and drug products required for registration trials.

IFx-Hu2.0 is comprised of 1) the Plasmid DNA (pAc/emm55) in TE Buffer Drug Product (DP) with 10% Dextrose Injection. and 2) the Cationic Polymer DP with 10% Dextrose Injection. The Plasmid DNA (pAc/ emm55) in TE Buffer DP utilizes the Cationic Polymer DP as a transfectant agent excipient, and IFx-Hu2.0 is complexed at the site prior to patient administration. TuHURA has completed the FDA-required mixing studies demonstrating the mixing process consistently produces a product that meets a set of quality attributes. IFx- Hu2.0 preparation instructions are included in the pharmacy manual to ensure mixing at the site prior to administration results in reliably produced drug product with consistent material properties. In addition, the FDA-required potency and stability assays have been developed, qualified, and/or validated supporting product release and stability, which meets cGMP requirements for use in our Phase 3 registration trial.

TuHURA assumed from Kineta a manufacturing agreement with Samsung Biologics to provide manufacturing services, including CTM drug substance and drug product manufacturing and stability testing for TBS-2025. Samsung has no commercial rights to TBS-2025 or any other assets acquired from Kineta.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available. We have sought patent protection in the United States and internationally related to our IFx-Hu2.0 platform technology, and we license from third parties the patents and patent applications relating to our tumor microenviroment modulators technology.

We expect to file additional patent applications in support of current and new clinical candidates, as well as new platform and core technologies. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending any such patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The terms of individual patents depend upon the statutory term of the patents in the countries in which they are issued. In most countries in which we file, including the United States, the patent term is 20 years from the earliest filing of a non-provisional patent application. In the United States, a patent term may be lengthened by patent term adjustment ("PTA"), which compensates a patentee for administrative delays by the USPTO in examining and granting a patent. Conversely, a patent term may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits patent term restoration to account for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the subject drug candidate is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other foreign jurisdictions. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment that such extensions should be granted, and if granted, the length of such extensions.

In some instances, we have submitted and expect to submit patent applications directly to the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We expect to file U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. A designated authority performs an initial search and issues a non-binding opinion as to the patentability of the subject matter. The opinion may be used to evaluate the chances of success of national phase applications in various jurisdictions, thereby informing the development of a global filing strategy.

Although a PCT application does not itself issue as a patent, it allows the applicant to conveniently file applications in any of the member states through national-phase applications. At the end of a period of 30-31 months from the earliest priority date of the patent application (varies by jurisdiction), individual applications can be filed in any of the PCT member states/regions. Use of the PCT system is more cost-effective than direct foreign filings and permits applicants greater flexibility with respect to budgeting and the selection of foreign jurisdictions.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes, and compositions, given existing

patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

The patent positions of biotechnology companies are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material 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, see "*Risk Factors – Risks Relating to Our Intellectual Property*."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/ or clinical candidates.

Company-owned Intellectual Property

As of December 31, 2025, we had at least 33 issued patents over 13 jurisdictions, and 10 pending applications (2 U.S. utility patent applications, a pending PCT application and 7 foreign patent applications). Most of such patents and patent applications relate to our IFx technology platform. The following is a summary of our issued patents and pending patent applications as of December 31, 2025 by patent family.

Patent Family	Description	Application/Publication/ Patent Number	Filing Date	Issue Date/Status	Earliest Expected Expiration Date	Type of Patent Protection
DNA Vector and Transformed Tumor Cell Vaccines	Whole cell and DNA cancer vaccines	PCT/US2015/018688 (WO 2015/134577)	03/04/2015	Nationalized in CH, DE, DK, EP, FR, GB, HK, IE, NL, NO, SE, US	03/04/2035	Use Composition Composition
		US 9,555,088 US 9,839,680 US 10,391,158 US 10,751,400	07/07/2016 01/30/2017 12/11/2017 08/26/2019	Issued 01/31/2017 Issued 12/12/2017 Issued 08/27/2019 Issued 08/25/2020	03/4/2035 03/4/2035 03/4/2035 03/4/2035	Use
Cancer Vaccine Comprising mRNA Encoding a M-Like-Protein	Next generation cancer vaccine using mRNA encoding a bacterial antigen to prime anti- cancer immune responses	PCT/US2016/033235 (WO 2016/187407)	05/19/2016	Nationalized in AU, CA, CH, CN, DE, DK, EP, FR, GB, HK, IE, JP, NL, NO, SE, US		Use Composition Composition/use
		US 9,636,388 US 10,682,401 US 18/060,605	07/28/2016 05/01/2017 12/01/2022	Issued 05/02/2017 Issued 06/16/2020 pending	05/19/2036 05/19/2036 05/19/2036	
Modified mRNA for Multicell Transformation	Next generation cancer vaccine using mRNA encoding a bacterial antigen to prime anti- cancer immune responses	PCT/US2021/031204 (WO 2021/226413)	05/7/2021	Nationalized in CN, JP, CA, IN, AU, EP, KR To be filed in HK	05/7/2041	
Exosome Delivery of Cancer Therapeutics	Production and use of exosome preparations to systemically deliver pDNA and/or	US 18/055,724	11/15/2022	Published/pending		Composition/use

Materials and Methods for Treatment of Melanomas and Other Cancers	Anti-cancer vaccine compositions comprising nucleic acids and methods of treating immune checkpoint inhibitor therapy resistant cancers.	PCT/US2025/21863	03/27/2025	Published/pending	03/27/2045	Composition/Use

Intellectual Property Acquired in Kineta Merger

As of December 31, 2025, our patent portfolio acquired from Kineta as it pertains to TBS-2025 included fourteen (14) national phase applications in the KVA-001 patent family related to TBS-2025. The countries are as follows: U.S., Australia, Brazil, Canada, China, Europe (European Patent Office ("EPO")), Hong Kong, Israel, India, Japan, Korea, Mexico, Russia, and Singapore. Its estimated expiration date without any patent term adjustment or extension is 20 years from filing, i.e., February 18, 2042.

The table below summarizes the high-level filing strategy of our existing patent portfolio for the TBS-2025 related assets acquired from Kineta:

	VISTA patents (TBS-2025 f/k/a KVA12123)
Patent Family	**KVA-001**
Composition of matter	Y
Methods of Manufacturing	Y
Sequences/Structure	Y
Indications	Y
Specification on use (mono or combo)	Y
Binding characteristics	Y
Immune cell regulation	Y
Physiologic properties	Y
Discovery Candidates	To be added on a rolling basis

We strive to protect the proprietary technologies that we believe are important to TBS-2025, including by seeking, maintaining and defending patent rights, whether developed internally or in conjunction with or in- licensed from third parties. As to TBS-2025, we also rely on trade secrets relating to our monoclonal antibodies, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of innate immunity and fully human antibodies

As more fully described above, as of December 31, 2025, our patent portfolio related to TBS-2025 included 14 U.S. and foreign applications, which entered national phase in 2023.

Licensed Intellectual Property Rights Relating to DOR Technology

TuHURA licenses the intellectual property rights relating to its DOR technology platform under exclusive license agreements with H. Lee Moffitt Cancer Center and Research Institute ("Moffitt Cancer Center") and the West Virginia University Research Corporation ("WVURC"). In particular, TuHURA is a party to a March 2019 Exclusive License Agreement with Moffitt Cancer Center under which, as amended, we license patent rights co- owned by Moffitt and University of South Florida relating to ADCs for immunotherapy and Delta receptor targeted agents for molecular imaging and immunotherapy of lung cancer. TuHURA is a party to a second Exclusive License Agreement entered into in April 2021 under which, as amended, we license Moffitt's interest in certain patent rights relating to the applicability of TuHURA's Delta receptor technology to the tumor microenvironment (these patent rights are co-owned by Moffitt and us). TuHURA is a party to a September 2022 Restated and Amended Exclusive License Agreement with WVURC pursuant to which TuHURA licenses from WVURC certain patent rights (including WVURC's

rights under one patent that is jointly owned by WVURC and the company) relating to Delta receptor targeted agents for molecular imaging and cancer immunotherapy. These license agreements were originally entered into with Moffitt and WVURC by TuHURA Biopharma which assigned its interest under the agreements to TuHURA as a part of the acquisition of certain TuHURA Biopharma assets in January 2023. The following are summaries of the material terms of these license agreements:

2019 License Agreement with Moffitt Cancer Center

In March 2019, TuHURA Biopharma, as predecessor in interest to the Company, entered into an Exclusive License Agreement with Moffitt Cancer Center, which agreement was amended in September 2019, April 2021 and August 2022 (as amended, the "2019 Moffitt Agreement"), for the worldwide, exclusive license of patents for the development, commercialization and marketing of products derived from Moffitt's rights to patents entitled "Conjugates for Immunotherapy" and "A Delta-Opioid Receptor Targeted Agent For Molecular Imaging And Immunotherapy Of Lung Cancer" (the "2019 Moffitt Licensed Patents"). The exclusive nature of the granted licenses are subject to customary reservations by Moffitt for non-commercial research, development, and academic purposes. The licenses granted by Moffitt are sublicensable by us to affiliates and third parties, subject to certain requirements, including providing Moffitt with a copy of each executed sublicense agreement and ensuring that the sublicensee complies with the terms of the 2019 Moffitt Agreement.

Pursuant to the terms of the 2019 Moffitt Agreement, in partial consideration of Moffitt's grant of the rights and licenses, TuHURA Biopharma paid to Moffitt one-time, non-refundable license issue fees of $100,000 and $30,000. Additionally, TuHURA Biopharma issued shares of its common stock to Moffitt as additional consideration, which were exchanged for 146,397 shares of our common stock as a part of the TuHURA Biopharma asset acquisition. We are obligated to pay Moffitt an annual license maintenance fee not in excess of $50,000 per year until annual minimum royalty payments commence following commercial sales of licensed products.

Also under the 2019 Moffit Agreement, we are required to make the following additional payments:

- Various milestone royalty payments based on specified development, approval, commercialization, and sales milestones, which payments range from $150,000 to $400,000 for milestones relating to the commencement of clinical trials up to $3.0 million to $5.0 million based on sales thresholds in excess of $1.0 billion in sales;

- Running royalties based on net sales of licensed products with a royalty percentage in the middle-single digit and with escalating minimum annual royalties that do not exceed $0.5 million per year; and

- Payment of all patent prosecution and maintenance costs and fees for the licensed patents.

The term of the 2019 Moffitt Agreement will be until the later of (i) the date on which the last of the licensed patents expire, or (ii) twenty (20) years after the date of the 2019 Moffitt Agreement. We may unilaterally terminate the 2019 Moffitt Agreement at any time on six (6) months' notice to Moffitt, provided that all payments due by us at that time have been made through the effective date of termination. Additionally, we may terminate the agreement with written notice to Moffitt in the event Moffitt commits a material breach and such breach is not cured within sixty (60) days following Moffitt's receipt of such notice. Moffitt has the right to terminate, or convert all exclusive licenses to nonexclusive licenses in the event we: (x) fail to make payments due under the agreement within thirty (30) days following notice from Moffitt; (y) commit a material breach that is not cured, or capable of being cured, within sixty (60) days after receipt of notice from Moffitt; (z) or challenge the validity of any of the 2019 Moffitt Licensed Patents before a court or other administrative agency in any jurisdiction. Upon any termination prior to the expiration of the agreement for any reason, all licenses and rights granted pursuant to the agreement will automatically terminate. At the request of Moffitt, we are obligated to provide all materials, clinical results, regulatory submissions, registrations and any other related filings for the 2019 Moffitt Licensed Patents, and all data used to support the same, to Moffitt.

2021 License Agreement with Moffitt Cancer Center

In April 2021, TuHURA Biopharma, as predecessor in interest to us, entered into an Exclusive License Agreement with Moffitt, which agreement was amended in August 2022 (collectively, the "2021 Moffitt Agreement"), for the worldwide, exclusive, license to Moffitt's rights under a jointly-owned patent entitled "Delta Opioid Receptor Antagonist Reprogram Immunosuppressive Microenvironment to Boost Immunotherapy" (the "2021 Moffitt Licensed Patent") for the development, commercialization and marketing of products from covered claims of the 2021 Moffitt Licensed Patent. The exclusive nature of the licenses granted are subject to customary reservations by Moffitt for non-commercial research, development, and academic purposes. The licenses granted by Moffitt are sublicensable by the Company to affiliates and third parties, subject to certain requirements, including providing Moffitt

with a copy of each executed sublicense agreement, and ensuring that the sublicensee comply with the terms of the 2021 Moffitt Agreement.

Pursuant to the terms of the 2021 Moffitt Agreement, in partial consideration of Moffitt's grant of the rights and licenses, TuHURA Biopharma paid to Moffitt a one-time, non-refundable license issue fee of $12,500. Additionally, TuHURA Biopharma issued shares of its common stock to Moffitt as additional consideration, which were exchanged for 195,465 shares of our common stock as a part of the TuHURA Biopharma asset acquisition. We are obligated to pay Moffitt an annual license maintenance fee not in excess of $25,000 per year until annual minimum royalty payments commence following commercial sales of licensed products.

We are also required to make the following additional payments:

- Various milestone royalty payments based on specified development, approval, commercialization, and sales milestones, which payments range from $37,500 to $100,000 for milestones relating to the commencement of clinical trials up to $750,000 to $1.25 million based on sales thresholds in excess of $1.0 billion in sales; and

- Running royalties based on net sales of licensed products with a royalty percentage in the middle-single digit and with escalating minimum annual royalties that do not exceed $0.1 million per year; and

- Payment of all patent prosecution and maintenance costs and fees for the licensed patents.

The term of the 2021 Moffitt Agreement will be until the later of (i) the date on which the last of the patents expire, or (ii) twenty (20) years after the date of the 2021 Moffitt Agreement. We may unilaterally terminate the 2021 Moffitt Agreement at any time on six (6) months' notice to Moffitt, provided that all payments due by us at that time have been made through the effective date of termination. Additionally, we may terminate the agreement with written notice to Moffitt in the event Moffitt commits a material breach and such breach is not cured within sixty (60) days following Moffitt's receipt of such notice. Moffitt has the right to terminate, or convert all exclusive licenses to nonexclusive licenses in the event we: (x) fail to make payments due under the agreement within thirty (30) days following notice from Moffitt; (y) commit a material breach that is not cured, or capable of being cured, within sixty (60) days after receipt of notice from Moffitt; (z) or challenge the validity of any of the 2021 Moffitt Licensed Patent before a court or other administrative agency in any jurisdiction. Upon any termination prior to the expiration of the agreement for any reason, all licenses and rights granted pursuant to the agreement will automatically terminate. At the request of Moffitt, we are obligated to provide all materials, clinical results, regulatory submissions, registrations and any other related filings for the 2021 Moffitt Licensed Patent, and all data used to support the same, to Moffitt.

License Agreement with West Virginia University Research Corporation

In January 2023 but with an effective date of September 2022, TuHURA Biopharma, as predecessor in interest of us, entered into a Restated and Amended Exclusive License Agreement with WVURC (the "WVU Agreement"), which terminated and replaced the prior agreement between WVURC and TuHURA Biopharma. The WVU Agreement provides for the exclusive commercialization rights relating to Delta receptor targeted agents for WVURC patent rights relating to molecular imaging and cancer immunotherapies (the "WVU Patents"). Under the WVU Agreement, among other rights, WVURC granted us a worldwide, exclusive right, with limited sublicense rights, to develop and commercialize the WVU Patents in accordance with the milestone schedule therein.

As partial consideration for the rights granted under the WVU Agreement, TuHURA Biopharma previously paid a non-refundable, upfront fee of $50,000. Under the terms of the WVU Agreement, we are required to pay WVURC a tiered running royalty in the low-to-mid single digit percentages based on levels of net sales of licensed products, including the net sales of sublicensees, with customary anti-stacking provisions. We are also required to pay annual fees of $30,000 or less and is required to fund all patent prosecution and maintenance costs and fees for the licensed patents.

The term of the WVU Agreement will expire on the later of: (i) the expiration of the date of the last to expire of the WVU Patents or (ii) twenty (20) years from the first commercial sale of a licensed product derived from the WVU Patents, unless earlier terminated pursuant to its terms. We may unilaterally terminate the WVU Agreement upon written notice to WVURC at any time on six (6) months' notice to WVURC, provided that all payments due by us at that time have been made through the effective date of termination. Additionally, we may terminate the agreement with written notice to WVURC in the event WVURC commits a material breach and such breach is not cured within sixty (60) days following WVURC's receipt of such notice. WVURC has the right to terminate, or convert all exclusive licenses to nonexclusive licenses in the event we fail to make payments due under the agreement within thirty (30) days following notice from WVURC; commit a material breach that is not cured, or capable of being cured, within ninety (90) days after receipt of notice from WVURC; or challenge the validity of any of the WVU Patents before a court or other

administrative agency in any jurisdiction. Upon any termination prior to the expiration of the WVU Agreement for any reason, all licenses and rights granted pursuant to the agreement will automatically terminate.

The following is a summary of the patent rights licensed from Moffitt Cancer Center and WVURC:

Patents Under License Agreement with West Virginia University Research Corporation

PCT/US2022/070893 (filed 3/1/2022) – "A Delta-Opioid Receptor Targeted Agent for Molecular Imaging and Immunotherapy of Cancer"

Applicant: West Virginia University Board of Governors on behalf of West Virginia University

Summary: Relates to molecular conjugates of anticancer compounds and imaging agents and methods of use as a cancer therapy comprising an antagonist of a cell surface opioid receptor such as a delta opioid receptor (DOR), specific to a target cell, an imaging agent, and an immune modulatory molecule, such as a T cell modulator, conjugated to the DOR antagonist.

Earliest Expected Expiration Date: 3/1/2042

Country	App. No.	Filing Date	Grant Date	Patent No.	Status
AU	2022229527	8/23/2023			Pending
CA	3209499	8/23/2023			Pending
CN	202280018635.7	10/8/2023			Pending
HK	62024085712.3	1/19/2024			Pending
EPO	22764254.3	9/28/2023			Pending
IN	202317063261	9/20/2023			Pending
JP	2023-553656	8/31/2023			Pending
KR	10-2023-7033553	9/27/2023			Pending
US	18/548724	9/1/2023			Pending

PCT/US2022/070894 (filed 3/1/2022) – "A Delta-Opioid Receptor Targeted Agent for Molecular Imaging and Immunotherapy of Cancer"

Applicants: West Virginia University Board of Governors on behalf of West Virginia University and TuHURA Biopharma Inc.

Summary: Relates to molecular conjugates of anticancer compounds and imaging agents and methods of use as a cancer therapy comprising an antagonist of a cell surface opioid receptor such as a DOR or agents that are kinase inhibitors or JAK/STAT3 inhibitors, specific to a target cell, an imaging agent, and an immune modulatory molecule, such as a T cell modulator, conjugated to the DOR antagonist or kinase inhibitors or JAK/STAT3 inhibitors.

Earliest Expected Expiration Date: 3/1/2042

Country	App. No.	Filing Date	Grant Date	Patent No.	Status
AU	2022231182	8/23/2023			Pending
CA	3210556	8/31/2023			Pending
CN	202280018634.2	10/20/2023			Pending
EPO	22764255.0	9/28/2023			Pending
IN	202317062268	9/15/2023			Pending
JP	2023-553657	8/31/2023			Pending
KR	10-2023-7033611	9/27/2023			Pending
US	18/548729	9/1/2023			Pending

Patents Under License Agreements with H. Lee Moffitt Cancer Center

PCT/US2017/030962 (filed 5/4/2017) – "A Delta-Opioid Receptor Targeted Agent for Molecular Imaging and Immunotherapy of Cancer"

Applicants: University of South Florida and the H. Lee Moffitt Cancer Center

Summary: Relates to compounds comprising at least one delta-opioid receptor ligand, such as Dmt-Tic, conjugated to an anti-PDl checkpoint inhibitor antibody and Dmt-Tic-antibody conjugates and methods of use thereof to treat cancer.

Earliest Expected Expiration Date: 5/4/2037

Country	App. No.	Filing Date	Grant Date	Patent No.	Status
US	16/098906	11/5/2018	10/1/2019	10426843	Granted
US	16/587720	9/30/2019			Abandoned
US	17/830781	6/2/2022	1/7/2025	12186404	Granted
US	19/011258	1/6/2025			Pending

PCT/US2015/038057 (filed 6/26/2015) – "Conjugates for Immunotherapy"

Applicants: University of South Florida and the H. Lee Moffitt Cancer Center

Summary: Relates to molecular conjugates comprising agonists of cell surface receptors specific to a target cell, such as DOR agonists, and an immune effector, such as a T cell modulator, compositions comprising the same and methods of treating a disease, such as cancer, by administering the molecular conjugates.

Earliest Expected Expiration Date: 6/26/2035

Country	App. No.	Filing Date	Grant Date	Patent No.	Status
US	15/321316	12/22/2016	10/22/2019	10449227	Granted
US	16/659207	10/21/2019			Abandoned
US	17/889456	8/17/2022			Abandoned
US	18/130049	4/3/2023			Pending

PCT/US2021/022464 (filed 3/16/2021) – "Delta opioid receptor antagonists reprogram immunosuppressive microenvironment to boost immunotherapy"

Applicants: H. Lee Moffitt Cancer Center

Summary: Relates to (a) methods of stimulating endogenous T cells, increasing the efficacy of adoptive immunotherapy, or reprogramming immunosuppressive tumor microenvironments, immunosuppressive myelopoiesis, or myeloid-derived suppressor cells by administering a DOR antagonist; (b) combination immunotherapies comprising an adoptive immunotherapy or an immune system activator and a DOR antagonist and methods of using the same to treat cancer; (c) methods of treating autoimmune disease or microbial infection by administering a DOR agonist, optionally with an immunosuppressor; and (d) combination therapies comprising a DOR agonist and an immunosuppressor.

Earliest Expected Expiration Date: 3/16/2041

Country	App. No.	Filing Date	Grant Date	Patent No.	Status
US	17/912300	9/16/2022			Pending

Employees and Human Capital Resources

As of December 31, 2025, we had 22 full-time employees and no part-time employees. Of these employees, 18 were engaged in research and development activities. The majority of our employees are based in Tampa, Florida. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

TuHURA's human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

TuHURA's principal office is located in Tampa, Florida. TuHURA currently leases approximately 12,199 square feet of office and laboratory space under a lease that is due to expire in March 2028. TuHURA believes that such office and laboratory space will be sufficient for TuHURA’s planned operations for the foreseeable future.

Government Regulation and Product Approval

Therapeutic products are subject to rigorous regulation by the FDA and other governmental agency regulations in the United States and in foreign countries. Noncompliance with applicable requirements can result in import detentions, fines, civil monetary penalties, injunctions, suspensions or losses of regulatory approvals or licenses, recall or seizure of products, operating restrictions, denial of export applications, governmental prohibitions on entering into supply contracts, and criminal penalties and prosecution. Failure to obtain regulatory approvals or the restriction, suspension or revocation of regulatory approvals or licenses, as well as any other failure to comply with regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations. In connection with seeking therapeutic approval, we will have to comply with the many regulations and requirements associated with the conduct of preclinical and clinical trials, the FDA application process, FDA manufacturing requirements for investigational products, and testing. Upon approval of a New Drug Application (NDA), Biologics License Application (NDA/BLA), and similar approvals in other jurisdictions, there will be additional regulations that must be complied with, including regulations relating to the packaging, distribution, labelling, marketing and claims of our potential products. These later regulations are not only found in federal regulation but many states and, of course, foreign countries.

The U.S. FDA Process

The FDA regulates the clinical trials and design of therapeutics to ensure that medical products distributed in the United States are safe and effective for their intended uses. The application process for a new therapeutic is highly regulated.

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation by relevant authorities, including the FDA. Our potential products will be regulated as combination products, depending on the product composition and mechanism of action, or biologics. With this classification, commercial production of its potential products will need to occur in registered and licensed facilities in compliance with current good manufacturing practices (cGMP) established by the FDA.. The FDA categorizes human cell- or tissue-based products as either minimally manipulated, homologous use, combination with other articles, or systemic effect and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization.

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, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of pharmaceutical and/or biopharmaceutical products such as those we are developing. Our candidates must be approved by the FDA

before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in a foreign country. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Product Development Process

In the United States, the FDA regulates pharmaceutical and/or biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and their respective implementing regulations. Products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a pharmaceutical and/or biological products may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to Good Laboratory Practices, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an investigational new drug, or IND, application, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as Good Clinical Practice, or GCP, and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of an NDA/NDA/BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical and/or biological products is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current Good Tissue Practices, or cGTPs, for the use of human cellular and tissue products;
- potential FDA audit of the trial and clinical trial sites that generated the data in support of the NDA/NDA/BLA; and
- FDA review and approval, or licensure, of the NDA/NDA/BLA.

Preclinical studies

Before testing any pharmaceutical and/or biological products candidate, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as non-clinical studies, include laboratory evaluations (product chemistry, toxicity and formulation), as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted (i.e., long term toxicology or additional studies can run in parallel). An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before human clinical trials may begin.

Human clinical trials in support of a BLA

Clinical trials involve the administration of the pharmaceutical and/or biological products candidate to human research subjects under the supervision of qualified investigators, generally licensed physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection, inclusion and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. An IND becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a pharmaceutical and/or biological products/candidate at any time before or during a clinical trial due to safety concerns or non-compliance. If the FDA imposes a clinical hold, the trial may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research participants provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent form that must be signed by each clinical trial subject or the participant's legal representative and must monitor the clinical trial until completed. For certain clinical trials involving gener therapy or recombinant DNA, they also must be reviewed by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on the ClinicalTrials.gov data registry. Information related to the investigational product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed for one year, with possible extensions in some cases for up to two years after the date of completion of the trial.

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

- phase 1. The investigational product candidate is initially introduced into human subjects to test for safety, dosage tolerance, absorption, metabolism, distribution and excretion. The initial human testing is often conducted in patients, rather than in healthy volunteers, in the case of products for severe or life-threatening diseases.

- phase 2. The product is evaluated in a limited patient population to identify possible safety risks (adverse effects), optimize dosing and preliminarily evaluate the efficacy of the product for specific targeted diseases.

- phase 3. Clinical trials are undertaken in an expanded patient population to further evaluate dosage, clinical efficacy, and safety, often at geographically dispersed trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the investigational product and provide, if appropriate, an adequate basis for product labeling. These trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing.

Postmarketing Requirements (PMRs) and Postmarking Commitments (PMCs), sometimes referred to as phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. In certain instances, the FDA may mandate the performance of phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trial must be submitted at least annually to the FDA and more frequently if serious adverse events, or SAEs, occur. The FDA or the trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research participants 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

clinical protocol, GCP, or other IRB requirements, or if the investigational product has been associated with unexpected serious harm to patients. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor known as the data safety monitoring board or committee. This group provides recommend continuation, modification, or termination for whether a trial may move forward at designated checkpoints.

During the development of a new pharmaceutical and/or biological products, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of phase 2, and before submission of a NDA/NDA/BLA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide guidance, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end of phase 2 meeting to discuss their phase 2 clinical results with the agency and to present their plans for the pivotal phase 3 studies that they believe will support approval of the new drug or biological product.

Human immunotherapy products are rapidly evolving category of therapeutics. Because this is a relatively new and expanding area of novel therapeutic interventions, there can be no assurance as to the length of the clinical trial period, the number of participants the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of immunotherapy products, or that the data generated in these trials will be acceptable to the FDA to support marketing approval.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the pharmaceutical and/or biological products as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the final product does not undergo unacceptable deterioration over its retest date or shelf life.

U.S. Review and Approval Processes

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, and controls (CMC) are submitted to the FDA as part of an NDA/NDA/BLA requesting approval to market the product for one or more indications. An NDA/NDA/BLA must contain proof of the product candidate's safety, purity, potency and potency (efficacy) for its proposed indication or indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the NDA/NDA/BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended, or PDUFA, each NDA/NDA/BLA must be accompanied by a significant user fee, and the sponsor of an approved NDA/NDA/BLA is also subject to an annual program fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDA/NDA/BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

According to the goals and policies for original NDA/NDA/BLAs agreed to by the FDA under PDUFA, the FDA has ten months (Standard timeframe) from the accepted filing date to complete an initial review of the application and respond to the applicant, and six months from the filing date for an application with priority review. For all NDA/NDA/BLAs, the ten and six-month time periods run from the filing date; for most other original applications, the ten and six-month time periods run from the submission date. Despite these review goals, it is not uncommon for FDA review of a NDA/NDA/BLA to extend beyond the goal date.

Within 60 days following submission of the application, the FDA reviews an NDA/BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may Refuse-to-File (RTF) any NDA/NDA/BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA/NDA/BLA must be resubmitted with the additional information. The resubmitted application is 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 of the NDA/NDA/BLA. The FDA reviews the NDA/NDA/BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The review process

may be extended by the FDA for three additional months for major amendments or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

The FDA may refer applications for novel products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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 final decisions on approval. The FDA may independently analyze or validate submitted data, which could result in extensive discussions between the FDA and the applicant during the review process. The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the drug or biological product. The REMS 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 determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA NDA/NDA/BLA approval is contingent on agreeing to REMS, if required.

Before approving an NDA/NDA/BLA, the FDA will typically conduct a pre-approval inspection of the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are compliant with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the cGTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products (HCT/Ps), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the cGTP requirements is to ensure that cellular tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. Additionally, before approving an NDA/NDA/BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, cGTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA/NDA/BLA or supplement to a NDA/NDA/BLA must contain data to assess the safety and effectiveness of the product 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 grant deferrals for submission of data or full or partial waivers. A sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration is required to submit an initial Pediatric Study Plan, or iPSP, within sixty days of an end-of-phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the phase 3 or phase 2/3 clinical trial. The iPSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the iPSP. A sponsor can submit amendments to an agreed upon iPSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials or other clinical development programs. Unless otherwise required by regulation, the PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the NDA/BLA does not satisfy its regulatory criteria for approval and deny approval or may require additional clinical or other data and information. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. Based on the FDA's evaluation of the NDA/BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue either an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant may choose to either resubmit the NDA/BLA addressing all the deficiencies identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA/BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months

depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval from the FDA, the approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including phase 4 clinical trials, be conducted to further assess a product'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 trials 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.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, Breakthrough Therapy Designation, priority review designation, and regenerative medicine advanced therapy designation.

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 NDA/BLA 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 NDA or NDA/BLA. In addition, fast track designation may be withdrawn by the sponsor or rescinded by the FDA if the designation is no longer supported by data emerging from the clinical trial process.

In addition, with the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, Congress created a new regulatory program for product candidates designated by FDA as "breakthrough therapies" upon a request made by the IND sponsors. 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 of their respective marketing applications. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings with and providing advice to the product sponsor, which are intended to expedite the development and review of an application for approval of a breakthrough therapy.

Next, the FDA may designate a product for priority review if it is a drug or biologic that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original NDA/BLA from the date of filing.

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 and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

As part of the 21st Century Cures Act, congress created an accelerated approval pathway for regenerative medicine advanced therapies, or RMATs, which includes therapeutic tissue engineered products, human cell and tissue products, cell therapies and

combination products using any such therapies. The program is intended to facilitate expedited development and review of RMATs intended to address serious diseases or conditions.

A sponsor may request a RMAT designation from the FDA concurrently with or any time after the IND submission. The FDA has 60 calendar days to determine if the drug product meets the required criteria. Preliminary clinical evidence that the product has the potential to address a serious unmet need or condition is expected, is not required to indicate that the drug product may offer significant improvement over current therapies. The RMAT designation provides the same benefits of the fast track and breakthrough designation programs and programs may be eligible for priority review. Products with the RMAT designation may also be eligible for accelerated approval if pre-agreed criteria are met.

Accelerated Approval Pathway

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and 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 that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval are subject to the same statutory standards, but approval is based on surrogate endpoints reasonably likely to predict benefit.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA experience is evolving with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug. All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug 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 available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA/BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether the drug or biologic is no longer designated

as an orphan drug. More than one product candidate may receive an orphan drug designation for the same indication. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to seven years of orphan product exclusivity. During the seven-year exclusivity period, the FDA may not approve any other applications to market a product containing the same active moiety for the same disease, except in very limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Thus, orphan drug exclusivity could block the approval of one of our potential products for seven years if a competitor obtains approval of the same product as defined by the FDA and we are not able to show the clinical superiority of our product candidate or if our product candidate's indication is determined to be contained within the competitor's product orphan indication.

In addition, the FDA will not recognize orphan drug exclusivity if a sponsor fails to demonstrate upon approval that the product is clinically superior to a previously approved product for the same orphan condition, regardless of whether or not the approved product was designated an orphan drug or had orphan drug exclusivity.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our biological products, some of our US patents may be eligible for limited patent term extension. These patent term extensions permit a patent restoration term of up to five years as compensation for any patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The Patent Term Extension (PTE) period is generally one-half the time between the effective date of an IND, and the submission date of a NDA/BLA, plus the time between the submission date of a NDA/BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension, and the extension must be filed within 60 days of FDA approval. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity available in the United States and, if granted, it provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity or listed patents. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request does not require the sponsor to undertake the described studies.

Post-Approval Requirements

Any potential products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as off-label use), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses, if the physicians deem to be appropriate in their professional medical judgment, it is FDA's position that manufacturers cannot market or promote off-label uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including liability under federal fraud and abuse and civil and criminal false claims laws. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or a supplement, which may require the applicant to develop additional data or conduct additional preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a REMS to assure the safe use of the product. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial

promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the quality and long-term stability of the product. We expect to rely on third parties to produce clinical and commercial quantities of our potential products in accordance with cGMP regulations. However, the sponsor remains legally responsible for product quality and cGMP compliance. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities before any product is approved and our commercial products can be manufactured. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to risk-based, periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our contract development and manufacturing organizations, or CDMOs, that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA/BLA, including, among other things, voluntary recall and regulatory sanctions as described below.

Once approval of a product is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or other enforcement-related letters or clinical holds on post-marking (Phase 4) studies;
- refusal of the FDA to approve pending NDA/BLAs or supplements to approved NDA/BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

In addition, the Drug Supply Chain Security Act, or DSCSA, was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products depending on classification and product type. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10-year period that has been extended by a stabilization period extending enforcement discretion to November 2024. In the Fall of 2024, the FDA granted additional flexibility into 2025 based on the type of activities being performed. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Coverage, Pricing and Reimbursement

Sales of pharmaceutical products approved by the FDA will depend, in significant part, on the availability of third-party coverage and reimbursement for the products. Third-party payors include government healthcare programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the prices of products and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Further, there is no uniform policy for coverage and reimbursement in the United States by third-party payors. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or other comparable regulatory approvals.

Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development. Our product candidates may not be considered cost-effective. It is time consuming and expensive to seek coverage and reimbursement from third-party payors. Coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment, or HTA) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other EU Member States allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution (arbitrage between low-priced and high- priced member states) can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Other U.S. Health Care Laws and Regulations

Although we currently do not have any products on the market, our current and future arrangements with healthcare professionals, investigators, consultants, customers and third-party payors expose us to broadly applicable healthcare regulation and enforcement by the U.S. federal government and the states and foreign governments in which we conducts our business, such as fraud and abuse laws, transparency and health information privacy rules and regulations. These laws include, without limitation:

- The federal Anti-Kickback Statute – or AKS, 42 U.S.C. § 1320a-7b(b): the federal AKS is a criminal law which, prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for the furnishing of any item or service, or for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid. Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. The AKS covers the payers of kickbacks-those who offer or pay remuneration- as well as the recipients of kickbacks-those who solicit or receive remuneration. While each party's intent is a key element of their liability under the AKS, a person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. A conviction for violation of the AKS can result in criminal fines and/or imprisonment and requires mandatory exclusion from participation in federal healthcare programs;

- many US states have laws and regulations analogous to US federal fraud and abuse laws, such as individual state anti-kickback, fee-splitting and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payers;

- The Federal civil and criminal false claims laws, including the civil False Claims Act, or the FCA,—31 U.S.C. § § 3729-3733, which prohibits individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, and provides for civil whistleblower or qui tam actions that allow a private individual to file a lawsuit on behalf of the United State and entitles the whistleblower to a percentage of any recoveries. Under the FCA it is illegal to submit claims for payment to Medicare or Medicaid that an individual knows or should know are false or fraudulent; no specific intent to defraud is required. The civil FCA defines "knowing" to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Filing false claims may result in fines of up to three times the programs' loss plus $11,000 per claim filed. Under the civil FCA, each instance of an item or a service billed to Medicare or Medicaid counts as a claim. The fact that a claim results from a kickback or is made in violation of the Stark law also may render it false or fraudulent, creating liability under the civil FCA as well as the AKS or Stark law. Under the criminal FCA (18 U.S.C. § 287) penalties for submitting false claims include imprisonment and criminal fines; the OIG also may impose administrative civil monetary penalties for false or fraudulent claims;

- the federal civil monetary penalties law, or CMP (42 U.S.C. § 1320a-7a), prohibits a person from presenting or causing to be presented a claim that the provider knows or should know is improper, presenting a claim that the person knows or should know is for an item or service for which payment may not be made, and violating the AKS. The Office of Inspector General, or OIG of the US Department of Health and Human Services, or DHHS, may seek civil monetary penalties and sometimes exclusion for a wide variety of conduct and is authorized to seek different amounts of penalties and assessments based on the type of violation at issue;

- the federal Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, for covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their business associates and covered subcontractors that provide services to, or on behalf of, the covered entity that involve individually identifiable health information;

- The Physician Payments Sunshine Act (42 USC 1320a-7h) as known as "Open Payments" is a national disclosure program created by the Affordable Care Act, or ACA, that increases transparency into financial relationships between the health care industry (such as medical device manufacturers and pharmaceutical companies) and physicians or teaching hospitals. Drug, device, biological, and medical supply manufacturers, and group purchasing organizations are required to report payments or other transfers of value they make to physicians or teaching hospitals, as well as ownership or investment interests that a physician or his or her family members have in those entities. The Centers for Medicare & Medicaid Services, or CMS, collects data annually, and makes it publicly available and searchable online at openpaymentsdata.cms.gov. Applicable manufacturers are also required to report information related to payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. Individual states have their own "sunshine act reporting laws" which vary from state to state;

- the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials, which prohibit U.S. companies and their employees, officers, and representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official (including, potentially, healthcare professionals in countries in which we operate or may sell our products), government staff member, political party, or political candidate to obtain or retain business or to otherwise seek favorable treatment;

- per the Exclusion Statute (42 U.S.C. § 1320a-7) the OIG is legally required to exclude from participation in all Federal health care programs individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid; (2) patient abuse or neglect; (3) felony convictions for other health-care-related fraud, theft, or other financial misconduct; and (4) felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances. OIG has discretion to exclude individuals and entities on several other grounds, including misdemeanor convictions related to health care fraud other than Medicare or Medicaid fraud or misdemeanor convictions in connection with the unlawful manufacture, distribution, prescription, or dispensing of controlled substances; suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; engaging in unlawful kickback arrangements; and defaulting on health education loan or scholarship obligations. If a person or entity is excluded by OIG from participation in the Federal health care programs, then Medicare, Medicaid, and other Federal health care programs, such as TRICARE and the Veterans Health Administration, will not pay for items or services that are furnished, ordered, or prescribed. Excluded physicians may not bill directly for treating Medicare and Medicaid patients, nor may their services be billed indirectly through an employer or a group practice. In addition, if you furnish services to a patient on a private-pay basis, no order or prescription that you give to that patient will be reimbursable by any Federal health care program;

- the Physician Self-Referral Law, or the Stark Law - 42 U.S.C. § 1395nn, prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals. The Stark Law prohibits a physician from referring Medicare patients to an entity (including pharmacies) for the furnishing of "designated health services," if the physician or a member of the physician's immediate family has a direct or indirect "financial relationship" with the entity, unless a specific exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. The law further prohibits the entity from billing for any services that arise out of such prohibited referrals. Certain of these provisions are applicable to the referral of Medicaid patients as well. Designated health services include outpatient prescription drug services; clinical laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; DME and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; and inpatient and outpatient hospital services. The Stark Law is a strict liability statute thus the prohibition applies regardless of the rationale for the financial relationship and the reason for ordering the service; and analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by nongovernmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, such as the PhRMA Code, or the relevant compliance guidance promulgated by the federal government, in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures to the extent that those laws impose requirements that are more stringent than the Physician Payments Sunshine Act. In addition, state and local laws may require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Violations of any of such laws or any other governmental regulations that apply to us, may subject us to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, additional reporting requirements and oversight if the Company becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business.

Health Care Reform in the United States and Potential Changes to Health Care Laws

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

As previously mentioned, a primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other health care funding and applying new payment methodologies. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA that affect health care expenditures. There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical and biologic products. Notably, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the "CREATES Act." The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. Because generic and biosimilar product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic and biosimilar products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. The FDA also released a final rule on September 24, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. This final rule became effective November 30, 2020. In January 2024, FDA authorized the state of Florida's Section 804 Importance Program to allow Florida to import drugs from Canada for a period of two years. The ongoing impact of this and potentially other state programs is still unclear.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services.

Facilities

Our principal office is located in Tampa, Florida. We currently lease approximately 12,199 square feet of office and laboratory space under a lease that is due to expire in March 2028. We believe that such office and laboratory space will be sufficient for our planned operations for the foreseeable future.

Corporate Information

Our principal executive offices are located at 10500 University Center Drive, Suite 110, Tampa, Florida 33612. Our telephone number is (813) 875-6600. Our principal website address is www.tuhurabio.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is for convenience only and the information on the referenced website does not constitute a part of nor is incorporated by reference into this report.

Our reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, including our annual reports on Form 10-K, our quarterly reports on Form 10-Q and our current reports on Form 8-K, and amendments to those reports, are accessible through our website, free of charge, as soon as reasonably practicable after these reports are filed electronically with, or otherwise furnished to, the SEC. These SEC reports can be accessed through the "Investors" section of our website.

Information About Our Executive Officers and Directors

The following table sets forth the persons who serve as our executive officers and directors, and their ages as of March 31, 2026:

Name	Age	Position(s)
Executive Officers		
James Bianco, M.D.	69	Chief Executive Officer and Director
Dan Dearborn	59	Chief Financial Officer
Non-Employee Directors		
James Manuso, Ph.D., MBA	77	Director and Chairman of the Board
Alan List, M.D.	71	Director
George Ng	52	Director
Robert E. Hoffman	60	Director
Craig Tendler, M.D.	67	Director

Executive Officers

James Bianco, M.D. has served as our Chief Executive Officer and as a director since the completion of the Kintara Merger and for Legacy TuHURA since July 1, 2021. Dr. Bianco was also the founder, Chief Executive Officer and Chairman of Morphogenesis Biopharma, Inc., a biotechnology company, from its inception in November 2018 through its dissolution in January 2023, following the transfer of its assets to us. Dr. Bianco is a 30-year veteran of the biopharmaceutical industry. In 1991, Dr. Bianco founded CTI Biopharma, Inc. ("CTI") and from 1992 to 2016 was the Chief Executive Officer of CTI. During his tenure at CTI, Dr. Bianco was responsible for strategic portfolio development and identifying, acquiring, licensing, purchasing, or acquiring through international merger and acquisition, five drug candidates, four of which have since been approved by the FDA and with three receiving accelerated or conditional regulatory approval in the U.S. and/or E.U.

Dr. Bianco earned his M.D. from the Mount Sinai Icahn School of Medicine and completed his residency and chief residency at the Mount Sinai Medical Center in New York City. He completed his fellowship in Hematology/Oncology at the University of Washington/Fred Hutchinson Cancer Research Center (FHCRC) where he was appointed Assistant Professor of Medicine, Assistant Member FHCRC and Director of the Bone Marrow Transplant Unit at a "Hutch" affiliate (SVAMC).

Dan Dearborn joined Legacy TuHURA in 2018 as its Chief Financial Officer and has served in this role for our company since the completion of the Kintara Merger. Mr. Dearborn is a CPA with over 25 years of finance experience exclusively with health care and biotechnology companies. Prior to joining our company, from 2015 to 2017, Mr. Dearborn was Chief Financial Officer at MYMD Pharmaceuticals, Inc., an emerging biotechnology firm. Mr. Dearborn is an alumnus of Loyola University in Maryland and joined Ernst & Young early in his career. He was with Pharmerica, a long-term care pharmaceutical company, for fifteen years and

advanced quickly to a Director role. He then moved to BioDelivery Sciences International as Controller. During his time at BioDelivery Sciences International, the company signed two very large commercial partnership agreements and was listed on Nasdaq. Mr. Dearborn later joined Welldyne, Inc. ("Welldyne") as its Chief Financial Officer. Welldyne is a pharmacy benefit manager that also had several related health care businesses and employed associates in Florida and Colorado. During his time with Welldyne, the company was sold to Carlyle Group, Inc., one of the largest private equity firms in the world.

Non-Employee Directors

James S. Manuso, Ph.D., MBA, has served as a director of Legacy TuHURA since November 2022 and as our director and Chairman since the completion of the Kintara Merger. Dr. Manuso has also served as Chairman and Chief Executive Officer of Talfinium Investments, Inc., an investment entity and financial consultancy, since 2014. Since 2018, Dr. Manuso has served as managing member of Laurelside LLC, a family office, which he founded. Dr. Manuso has served on the board of Ocuphire Pharma, Inc., a public company (NASDAQ:OCUP) developing Nyxol in advanced clinical trials for the treatment of multiple visual disorders, since November 2020. From 2015 until 2018, Dr. Manuso served as President, Chief Executive Officer and Vice Chairman of RespireRx Pharmaceuticals Inc. (OTC QB:RSPI), a Phase 3-ready, clinical-stage respiratory and neurological pharmaceutical company. From July 2011 until October 2013, Dr. Manuso served as Chairman and Chief Executive Officer of Astex Pharmaceuticals, Inc. (Nasdaq:ASTX) and led the sale of Astex Pharmaceuticals, Inc. to Otsuka Pharmaceutical Co., Ltd. ("Otsuka Pharmaceutical"). In 2013, he was a senior mergers and acquisitions advisor to Otsuka Pharmaceuticals' executive management. Dr. Manuso has served as board chairman and chairman of the audit, governance and nominating, pricing and compensation committees of multiple companies' boards, including Biotechnology Industry Organization, Novelos Therapeutics, Inc., Merrion Pharmaceuticals Ltd. (MERR:IEX; Dublin, Ireland), Inflazyme Pharmaceuticals, Inc. (IZP-TSE; Vancouver, Canada), Symbiontics, Inc., which he co-founded (sold to BioMarin Pharmaceutical Inc. as ZyStor, Inc.), Montigen Pharmaceuticals, Inc., Quark Pharmaceuticals, Inc., Galenica Pharmaceuticals, Inc., Supratek Pharma, Inc., EuroGen, Ltd. (London, UK), where he was chairman, and the Greater San Francisco Bay Area Leukemia & Lymphoma Society, where he also served as vice president.

Dr. Manuso holds a B.A. with honors in Economics and Chemistry from New York University, a Ph.D. in Experimental Psychology and Genetics from the New School University, and an Executive M.B.A. from Columbia Business School. Dr. Manuso is the author of numerous chapters, articles and books on topics including health care cost containment and biotechnology company management.

George Ng has served as a director of Legacy TuHURA since February 2020 and as a director of our company since the completion of the Kintara Merger. Mr. Ng has also served as a director of Calidi Biotherapeutics, Inc. (NYSE American: CLDI) since October 2019 and as its President and Chief Operating Officer since February 1, 2022, as well as a director and Chief Executive Officer of Processa Pharmaceuticals, Inc. (Nasdaq: PCSA) since August 8, 2023. In addition, Mr. Ng is currently a partner at PENG Life Science Ventures since September 2013, a director, co-founder, and chief business officer at IACTA Pharmaceuticals, Inc. since January 2020. Mr. Ng's experience further includes serving in various executive-level positions for multiple publicly-traded and private global biotechnology and pharmaceutical firms. Mr. Ng previously served as a director of Inflammatory Response Research, Inc. from May 2019 to April 2020, as a director of Invent Medical Corp from July 2019 to January 2020, as a director of ImmuneOncia Therapeutics Inc. from June 2016 to 2019, and as a director of Virttu Biologics Limited from April 2017 to April 2019. Mr. Ng was also the Executive Vice President and Chief Administrative Officer of Sorrento Therapeutics, Inc. (Nasdaq: SRNE) from March 2015 to April 2019, the Co-Founder and President, Business of Scilex Pharmaceuticals Inc. from September 2012 to April 2019, and the Senior Vice President and General Counsel of BioDelivery Sciences International Inc. (Nasdaq: BDSI) from December 2012 to March 2015. Mr. Ng holds a JD degree from the University of Notre Dame School of Law, as well as a B.AS double degree in Biochemistry and Economics from the University of California, Davis.

Alan List, M.D. has served as a director of Legacy TuHURA since November 2022 and as director of our company since the completion of the Kintara Merger. Dr. List has also served as Chief Medical Officer of Precision BioSciences, Inc. (Nasdaq: DTIL) ("Precision BioSciences"), a clinical stage gene editing company, since April 2021 and, prior to that, had been a strategic clinical advisor to Precision BioSciences and its board since April 2020, providing advice regarding its clinical stage and pre-clinical allogeneic CAR T programs. Prior to joining Precision BioSciences, Dr. List served in various roles at the Moffitt Cancer Center, including as President and Chief Executive Officer from 2012 to December 2019, Executive Vice President, Physician in Chief from 2008 to 2012 and Chief of the Malignant Hematology Division from 2003 to 2008. Prior to joining the Moffitt Cancer Center, Dr. List held academic and clinical appointments at the University of Arizona. Dr. List is internationally recognized for his many contributions in the development of effective treatment strategies for myelodysplastic syndrome ("MDS") and acute myeloid leukemia. His pioneering work led to the development of Revlimid (lenalidomide), a transformational treatment for patients with MDS and multiple myeloma. Dr. List is the author of numerous peer-reviewed articles and books. He previously served as the President for the Society of Hematologic Oncology as well as a member of the MDS Foundation Board of Directors. Dr. List is also an active member of the American Society of Clinical Oncology, the American Society of Hematology and the American Association for Cancer Research. He

is a Charter Fellow in the National Academy of Inventors, an inductee in the Florida Inventors Hall of Fame. Dr. List received B.S. and M.S. degrees from Bucknell University and earned his M.D. from the University of Pennsylvania. He is board certified in internal medicine, hematology, and medical oncology.

Robert E. Hoffman served as a director of Kintara from April 2018 through the completion of the Kintara Merger, as Chairman of Kintara from June 2018 through the completion of the Kintara Merger, as Chief Executive Officer and President of Kintara from November 2021 through the completion of the Kintara Merger, and as interim Chief Financial Officer of Kintara from June 1, 2023 through the completion of the Kintara Merger. Mr. Hoffman was appointed to our board in connection with the completion of the Kintara Merger. He has served as a member of board of directors of ASLAN Pharmaceuticals, Inc. (Nasdaq: ASLN), a publicly-held, clinical-stage immunology focused biopharmaceutical company, since October 2018, and as a member of the board of directors of FibroGenesis, a clinical-stage regenerative medicine company, since April 2021. He has also served as a member of board of directors, on the audit committee, and on the Human Resources and compensation committee of Antibe Therapeutics Inc. ("Antibe"), a publicly-held clinical-stage biotechnology company, since November 2020, and as Chairman of Antibe's board of directors from May 2022 to April 2024. Mr. Hoffman served as Senior Vice President and Chief Financial Officer of Heron Therapeutics, Inc., a publicly-held pharmaceutical company, from April 2017 to October 2020. From July 2015 to September 2016, Mr. Hoffman served as Chief Financial Officer of AnaptysBio, Inc., a publicly-held biotechnology company. From June 2012 to July 2015, Mr. Hoffman served as the Senior Vice President, Finance and Chief Financial Officer of Arena Pharmaceuticals, Inc. ("Arena"), a biopharmaceutical company, prior to its acquisition by Pfizer Inc. in March 2022. From August 2011 to June 2012 and previously from December 2005 to March 2011, he served as Arena's Vice President, Finance and Chief Financial Officer and in a number of various roles of increasing responsibility from 1997 to December 2005. Mr. Hoffman formerly served as a member of the board of directors of Saniona AB, a biopharmaceutical company, from September 2021 to May 2022, and as a member of the board of directors of Kura Oncology, Inc., a cancer research company, from March 2015 to August 2021. He also previously served as a member of the board of directors of CombiMatrix Corporation, a molecular diagnostics company, MabVax Therapeutics Holdings, Inc., a biopharmaceutical company, and Aravive, Inc., a clinical stage biotechnology company. Mr. Hoffman serves as a member of the steering committee of the Association of Bioscience Financial Officers. Mr. Hoffman formerly served as a director and President of the San Diego Chapter of Financial Executives International and was an advisor to the Financial Accounting Standard Board (FASB) for 10 years (2010 to 2020) advising the United States accounting rulemaking organization on emerging issues and new financial guidance. Mr. Hoffman holds a B.B.A. from St. Bonaventure University.

Craig Tendler, M.D. was appointed as a member of our board of directors on March 10, 2025. Dr. Tendler is an experienced pharmaceutical and biotech industry professional. From January 2010 through December 2024, Dr. Tendler served as the Vice President, Oncology Clinical Development, Diagnostics, and Global Medical Affairs of Johnson & Johnson Innovative Medicine Research & Development where was responsible for creating and overseeing robust development plans, including optimal integration of biomarkers and diagnostics, and comprehensive data generation activities for all products in the oncology portfolio. During his tenure at Johnson & Johnson, Dr. Tendler and his team worked in collaboration with the FDA and the European Medicines Agency to secure worldwide approvals of transformational treatment in prostate cancer, hematologic malignancies, as well as for lunch and bladder cancer. He played an instrumental role in achieving 13 FDA breakthrough designations for accelerating the early development of promising investigational medicines intended for the treatment of serious oncology conditions.

Prior to joining Johnson & Johnson Innovative Medicine, Dr. Tendler served as the Vice President of Oncology Clinical Research and Chair of the Oncology Licensing Committee at the Schering-Plough Research Institute. In addition to his pharmaceutical industry experience, Dr. Tendler has served as Co-Chair of the Friends of Cancer Research Corporate Council, member of the Bloomberg New Economy International Cancer Coalition, and member of the Admissions Committee, Mount Sinai School of Medicine. Dr. Tendler was an Assistant Professor of Pediatrics/Hematology-Oncology at the Mount Sinai School of Medicine and a NIH physician-scientist grant recipient and research fellow at the National Cancer Institute in Bethesda, Maryland. Dr. Tendler earned his undergraduate degree from Cornell University and graduated from the Mount Sinai School of Medicine, New York City, with high honors and induction into the Alpha Omega Alpha Medical Society.

Information regarding the backgrounds of our directors is hereby incorporated by reference from our definitive Proxy Statement relating to our 2026 Annual Meeting of Stockholders, which Proxy Statement is anticipated to be filed within 120 days after the end of the Fiscal Year covered by this Annual Report.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our audited financial statements and the related notes, as well as our other public filings with the SEC, before deciding to invest in our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects, as well as the price of our common stock, could be materially and adversely affected.

SUMMARY OF RISK FACTORS

- We have a limited operating history, are not profitable and may never become profitable.
- We have expressed substantial doubt about 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.
- 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.
- Our product candidates will face significant competition and may be unable to compete effectively.
- Various government regulations could limit or delay our ability to develop and commercialize our products or otherwise negatively impact our business.
- The commercial potential of our products is difficult to predict. The market for any product, or for companion animal diagnostics and medical devices overall, is uncertain and may be smaller than we anticipate, which could significantly and negatively impact our revenue, results of operations and financial condition.
- Our ability to obtain intellectual property protection for our products is limited.
- We will rely on third parties to conduct certain portions of our development activities. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our product candidates.
- If we fail to attract and keep key personnel and members of management, we may be unable to successfully develop any of our existing or future product candidates, conduct our in-licensing and development efforts and commercialize any of our existing or future products.
- 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.
- We expect that the price of our common shares will fluctuate substantially.
- Our shares of common stock could be delisted from Nasdaq Capital Market.

An investment in our common stock involves a high degree of risk. In determining whether to purchase our common stock, an investor should carefully consider all of the material risks described below, together with the other information contained in this Annual Report before making a decision to purchase our securities. An investor should only purchase our securities if he, she or it can afford to suffer the loss of his, her or its entire investment.

Risks Relating to Our Business and Industry

We are a clinical-stage company and has a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical-stage pharmaceutical company and have no products approved for commercial sale. We employ a multi-indication immunomodulator platform (ImmuneFx) that utilizes both cell and gene therapies, together, to stimulate the immune system

to recognize and combat tumor cells. Although there have been significant advances in cell and gene-based immunotherapies, our immunomodulatory platforms are new and largely unproven. Our operations to date have been limited to organizing and staffing the Company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies, and conducting clinical trials. If one of our product candidates received regulatory approval, we would need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. In addition, our limited operating history, particularly in light of the rapidly evolving cancer immunotherapy field, may make it difficult to evaluate our current business and predict our future performance. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields. If it does not address these risks successfully, our business will suffer.

We have incurred significant losses since inception and expects to incur significant losses for the foreseeable future and may not be able to achieve or sustain profitability in the future.

We are not profitable and has incurred significant losses in each period since its inception, including net losses of $30.1 million for the year ended December 31, 2025, and $21.7 million for the year ended December 31, 2024. To date, we have financed our operations primarily through registered direct offerings, private placements of our common and preferred stock, and convertible notes. We have not commercialized any products and have never generated any revenue from product sales. We expect these losses to increase as we continue to incur significant research and development and other expenses related to our ongoing operations, seeks regulatory approvals for our product candidates, scales-up manufacturing capabilities and hires additional personnel to support the development of our product candidates and to enhance our operational, financial and information management systems.

A critical aspect of our strategy is to invest significantly in our technology platform to improve the efficacy and safety of our product candidates. To become and remain profitable, we must develop and eventually commercialize products with significant market potential, which it may never achieve. Even if we succeed in commercializing one or more of these product candidates, we will continue to incur losses for the foreseeable future relating to our substantial research and development expenditures to develop our technologies. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. If we do not achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the Company and could impair our ability to raise capital, maintain our discovery and preclinical and clinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute your ownership interest. A decline in the value of our could also cause you to lose all or part of your investment.

Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.

Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern. In our financial statements for the years ended December 31, 2025 and 2024, we concluded that our recurring losses from operations and need for additional financing to fund future operations raise substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2025 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional funding. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, limit, reduce or terminate our product development or future commercialization efforts of one or more of our product candidates, or may be forced to reduce or terminate our operations. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors and other financing sources may be unwilling to provide additional funding to it on commercially reasonable terms, if at all.

We have never generated any revenue from product sales for our human drug candidates and our ability to generate revenue from product sales and become profitable depends significantly on our success in numerous endeavors.

We have no products approved for commercial sale, has not generated any revenue from product sales, and does not anticipate generating any revenue from product sales until sometime after we have received regulatory approval for the commercial sale of a product candidate. Our ability to generate revenue and achieve profitability depends significantly on our success in many endeavors, including:

- completing research regarding, and nonclinical and clinical development of, our product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration (the "FDA"), or other regulatory agencies, domestic or foreign, or other comparable foreign authorities, to perform preclinical studies or clinical trials in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market of one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as it estimates, the indication approved by regulatory authorities is narrower than it expects, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we may never become profitable.

We will require substantial additional capital to finance our operations in the future. If we fail to obtain additional financing on acceptable terms or at all, we may be unable to complete the development and commercialization of our product candidates.

Our operations have required substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates, particularly as we advance the development of our product candidates, including our lead product candidate Ifx-Hu2.0 as a potential treatment for patients with melanoma, bladder and cervical cancers and TBS-2025, our VISTA inhibiting antibody. If we obtain orphan drug designation and marketing approval for Ifx-Hu2.0 or any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

As of December 31, 2025, we had cash and cash equivalents of $3.6 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments, together with the $7.0 million received in the first quarter from the December 2025 registered direct offering, should be sufficient to fund our operations through early third quarter of 2026. This estimate is based on assumptions that may prove to be materially wrong, and we could use our available capital resources sooner than we currently expect because of circumstances beyond our control. We may require additional capital for the further development and commercialization of our product candidates and may need to raise additional funds sooner if we choose to pursue additional indications or geographies for our product candidates or otherwise expand more rapidly than we presently anticipate. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all. Our ability to raise additional funding will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. In addition, our ability to obtain future funding when needed through equity financings, debt financings or strategic collaborations may be particularly challenging in light of the uncertainties and circumstances resulting from the ongoing military conflict between Russian and Ukraine, the ongoing conflict between Israel and Hamas, as well as the recent United States and Israeli air-based military campaigns in Iran, and the global impacts of such conflicts. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourself.

Any of the above events could significantly harm our business, prospects, financial condition, and results of operations and cause the price of shares of our common stock to decline.

The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses. Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing, and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us.

We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach may be different. The competition comes from both biotechnology firms and from major pharmaceutical companies. Many of these companies have substantially greater financial, marketing, and human resources than us. We also experience competition in the development of our immunotherapies from universities, other research institutions and others in acquiring technology from such universities and institutions.

In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and/or products developed using other technologies, some of which have completed numerous clinical trials.

The successful development of immunotherapies is highly uncertain.

Successful development of biopharmaceuticals is highly uncertain and depends on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including:

- clinical study results that may show the immunotherapy to be less effective than expected (e.g., the study failed to meet its primary endpoint) or to have unacceptable side effects;

- failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or preparation of Biologics License Application ("BLA"), discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues;

- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and

- the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized.

Success in preclinical and early clinical studies does not ensure that large-scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit, or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict. The evidence of clinical response rates received to date for Ifx-2.0, our principal product candidate, as well as the other clinical activity and results described in this Report, does not mean that Ifx-2.0 or any other product candidate has demonstrated, or that such clinical response data will predict, sufficient clinical efficacy and prove the required level of safety in order to receive FDA approval or any other required regulatory approval.

In addition, we have entered into a Special Protocol Assessment ("SPA") agreement with the FDA regarding the initiation of a single registration-directed trial utilizing the FDA's accelerated approval pathway for Ifx-2.0. An SPA agreement for such a trial does not increase the likelihood of marketing approval for the product and may not lead to a faster or less costly development, review, or approval process.

Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payors were not to provide adequate coverage and reimbursement levels for any of our products once approved, market acceptance and commercial success would be reduced.

Our technology platforms, including our proprietary, multi-indication immunomodulatory platform (ImmuneFx Ifx, and Delta receptor targeting ADCs) technologies are a new approach to treat cancer and other immune-related diseases that present significant challenges.

We have concentrated our research and development efforts on advancing a new generation of immunotherapies based on the Ifx and Delta receptor antibody drug conjugates ("ADC") platforms, and our future success is highly dependent on the successful development of our product candidates, which target cancer and other immune-related diseases. We cannot be sure that our Ifx or Delta receptor ADC platforms will yield satisfactory products that are safe and effective, scalable, or profitable.

Our technology could become subject to many of the challenges and risks that gene therapies face, including:

- regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future;

- the FDA could recommend follow-up observation period of up to 15 years for all patients who receive our treatment. We may need to adopt such an observation period for our product candidates; and

- clinical trials using genetically modified cells conducted at institutions that receive funding for recombinant DNA research from the U.S. National Institutes of Health (the "NIH") are subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee (the "RAC"). Although the FDA decides whether individual protocols may proceed, the RAC review process can impede the initiation of a clinical trial, even if the FDA has reviewed the study and approved its initiation.

Moreover, public perception of therapy safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment mechanics. Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Our immuno-oncology product candidates are based on novel technologies that target the tumor microenvironment ("TME"), which makes it difficult to predict the results, timing and cost of product candidate development and likelihood of obtaining regulatory approval.

Our TBS-2025, acquired in the acquisition of Kineta in June 2025, target the TME which is highly immunosuppressive. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates based on our platform technologies in clinical trials or in obtaining marketing approval thereafter, and use of our platform technologies may not ever result in marketable products.

In addition, the clinical trial requirements of the FDA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be less predictable, more expensive and longer than for other, better known or extensively studied pharmaceutical or other product candidates.

The immuno-oncology industry is also rapidly developing, and our competitors may introduce new technologies improving the immune response to cancer that render our technologies obsolete or less attractive. New technology could emerge at any point in the development cycle of our product candidates.

If our clinical trials with our immune-oncology product TBS-2025 do not show any functionality in the TME, our development plans, financial position, results of operations and prospects may be materially adversely affected.

While we plan to develop product candidates for use in solid tumors, our immuno-oncology product candidate may not show any functionality in the TME. The cellular environment in which solid tumor cells thrive is generally hostile to T cells due to factors such as the presence of immunosuppressive cells, humoral factors and limited access to nutrients. Our product candidates may not be able to access the solid tumor, and even if they do, they may not be able to exert anti- tumor effects in a hostile TME. In addition, the safety profile of our product candidates may differ in a solid tumor setting. As a result, our product candidate may not demonstrate efficacy in solid tumors. If we are unable to make its immuno-oncology product candidate function in tumors, our development plans, financial position, results of operations and prospects may be materially adversely affected.

Our near-term ability to generate product revenue is dependent on the success of one or more of our product candidates, each of which are at an early stage of development and will require significant additional clinical testing before we can seek regulatory approval and begin commercial sales.

Our near-term ability to generate product revenue is highly dependent on our ability to obtain regulatory approval of and successfully commercialize one or more of our product candidates. IFx-2.0 and TBS-2025 are in late and early stages, respectively, of development and will require additional clinical and nonclinical development, regulatory review, and approval in each jurisdiction in which we intend to market the products, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety, purity, and potency of the product candidates in humans. We cannot be certain that any of our product candidates will be successful in clinical trials and they may not receive regulatory approval even if they are successful in clinical trials.

Before we can generate any revenues from sales of our lead product candidates, we must complete the following activities for each of them, any one of which it may not be able to successfully complete:

- conduct additional preclinical and clinical development with successful outcomes;
- manage preclinical, manufacturing, and clinical activities;
- obtain regulatory approval from the FDA and other comparable foreign regulatory authorities;
- establish manufacturing relationships for the clinical and post-approval supply of the applicable drug candidate in compliance with all regulatory requirements;
- build a commercial sales and marketing team, either internally or by contract with third parties;
- establish and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- develop and implement marketing strategies for successful commercial launch of our product candidates, if, and when, approved;
- secure and maintain acceptance of our products, if, and when approved, by patients, from the relevant medical communities and from third-party payors;
- compete effectively with other therapies;
- establish and maintain adequate health care coverage and reimbursement from third-party payors;
- ensure continued compliance with any post-marketing requirements imposed by regulatory authorities, including any required post-marketing clinical trials or the elements of any post-marketing Risk Evaluation and Mitigation Strategy ("REMS"), that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of the product outweigh its risks;
- maintain continued acceptable safety profile of the product candidates following approval; and
- invest significant additional cash in each of the above activities.

If we are unable to address one or more of these factors in a timely manner or at all, we could experience significant delays in the successful commercialization of, or an inability to successfully commercialize, our product candidates, which would materially harm our business. If we do not receive regulatory approvals for one or more of our product candidates, we may not be able to continue our operations. Even if we successfully obtains regulatory approvals to manufacture and market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which it gains regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.

Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in reaching a consensus with regulatory agencies on trial design;

- the FDA may not allow us to use the clinical trial data from a research institution to support an investigational new drug ("IND") application if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in our clinical trials;

- our INDs have been approved in a timely manner thus far, however, the FDA may not agree with our approach and strategy, which could result in potential delays and changes to our regulatory strategy;

- we may be required to complete additional preclinical studies in human leukocyte antigens before we can proceed with our INDs;

- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

- delays in obtaining required Institutional Review Board ("IRB") approval at each clinical trial site;

- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or trial sites; developments on clinical trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- delays in recruiting suitable patients to participate in our clinical trials;

- failure by our CROs, other third parties, or us to adhere to clinical trial requirements;

- failure to perform in accordance with the FDA's current good clinical practice regulations ("cGCPs"), requirements, or similar applicable regulatory guidelines in other countries;

- delays in patients completing participation in a trial or returning for post-treatment follow-up;

- patients dropping out of a trial;

- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- the cost of clinical trials of our product candidates being greater than we anticipate;

- clinical trials of our product candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;

- delays in developing our manufacturing processes and transferring to new third-party facilities to support future development activities and commercialization that are operated by contract manufacturing organizations ("CMOs"), in a manner compliant with all regulatory requirements; and

- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or it may elect to, conduct additional trials to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

If we do not achieve our projected development and commercialization goals in accordance with our expected and announced timeframes, the commercialization of any of our product candidates may be delayed, and our business will be harmed.

Elsewhere in this Annual Report, we have provided timing estimates regarding the initiation of clinical trials and clinical development milestones, and the expected availability of data resulting from these trials for certain of our product candidates. We expect to continue to estimate the timing of these types of development milestones and our expected timing for the accomplishment of various other scientific, clinical, regulatory, and other product development objectives. From time to time, we may publicly announce the expected timing of some of these events. However, the achievement of many of these milestones and events may be outside of our control. These timing estimations are based on a variety of assumptions we make, which may cause the actual timing of these events to differ from the timing it expects, including:

- our available capital resources and our ability to obtain additional funding as needed;
- the rate of progress, costs, and results of our clinical trials and research and development activities;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA, European Medicines Agency (“EMA”), and other regulatory authorities and the timing of these approvals;
- our ability to access sufficient, reliable, and affordable supplies of materials used in the manufacture of our product candidates;
- the efforts with respect to the commercialization of our product candidates;
- securing of costs related to, and timing issues associated with, manufacturing our therapeutic candidates and, if any of our product candidates are approved, sales and marketing activities and the commercial manufacture of our product candidates; and
- circumstances arising from global supply chain issues, our manufacturers and the availability of raw materials needed for the research and development of our product candidates.

If we fail to timely achieve announced milestones, the commercialization of any of our product candidates may be delayed, and our business and results of operations may be harmed.

Failure to successfully identify, develop, and commercialize additional therapeutics or product candidates could impair our ability to grow.

Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of the product candidates in our current pipeline, we expect to continue to innovate and potentially expand our portfolio. Research programs to identify product candidates may require substantial additional technical, financial, and human resources and may not result in any new potential product candidates being identified. our success may depend, in part, upon our ability to identify, select, and develop promising product candidates and therapeutics. We may expend resources and ultimately fail to discover and generate additional product candidates suitable for further development. All product candidates are prone to risks of failure typical of biotechnology product development, including the possibility that a product candidate may not be suitable for clinical development due to its harmful side effects, limited efficacy, or other characteristics indicating that it is unlikely to receive approval by the FDA, the EMA, and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize new product candidates we have identified and explored, our business, prospects, financial condition, and results of operations could be adversely affected.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

The FDA standard for regular approval of a biologic generally requires two well-controlled Phase 3 studies or one large and robust, well-controlled Phase 3 study in the patient population being studied that provides substantial evidence that a biologic is safe and effective for its proposed indication. Phase 3 clinical trials typically involve hundreds of patients, have significant costs, and take years to complete. Product candidates 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 candidate 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 irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality 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 accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. Recently, we entered into the SPA agreement with the FDA for a single Phase 3 randomized placebo and injection controlled trial for IFx-2.0. We initiated the Phase 3 trial in June 2025. If our efforts to obtain approval for IFx-2.0 or any other product candidate is not successful, then we may be required to conduct additional clinical trials beyond those it contemplates, which would likely result in a longer time period to potential approval and commercialization of such product candidate (if approved) and would likely increase the cost of development of such product candidate, all of which could harm the company's competitive position in the marketplace and shorten the remaining term of applicable patent coverage after product approval.

As part of its marketing authorization process, the EMA may grant marketing authorizations on the basis of less complete data than is normally required, when, for certain categories of medicinal products, doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use ("CHMP"), to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk-benefit balance of the medicinal product is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be fulfilled; and

- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete nonclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public- health threats.

Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

The granting of a conditional marketing authorization will allow medicines to reach patients with unmet medical needs earlier than might otherwise be the case and will ensure that additional data on a product are generated, submitted, assessed, and acted upon. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the EMA or CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied.

Our clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or regular approval. The results of preclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

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

- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;

- we may be unable to demonstrate that our product candidates' risk-benefit ratios for their proposed indications are acceptable;

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

- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;

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

- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third-party manufacturer's facilities with which we contract for clinical and commercial supplies; and

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

Further, failure to obtain approval for any of the above reasons may be made more likely due to the novel nature of our technology. Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological drug products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also adequate duration of response, a delay in the progression of the disease, and/or an improvement in survival. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. We expect there may be greater variability in results for products processed and administered on a patient-by-patient basis, as anticipated for our product candidates, than for "off-the-shelf" products, like small molecule drugs which are not personalized for each patient. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

In addition, even if our clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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

As with most biological products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials.

The FDA or comparable foreign regulatory authorities could delay or deny approval of our product candidates for any or all targeted indications and negative side effects could result in a more restrictive label for any product that is approved. Side effects such as toxicity or other safety issues associated with the use of our product candidates could also require us or our collaborators to perform additional studies or halt development or sale of these product candidates.

If one or more of our product candidates receives marketing approval, and us or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, many potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approvals of such products;
- regulatory authorities may require the addition of labeling statements, specific warnings or a contraindications;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;

- we may be required to change the way such products are distributed or administered, or change the labeling of the products;

- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the products;

- we may decide to recall such products from the marketplace after they are approved;

- we could be sued and held liable for harm caused to individuals exposed to or taking our products; and

- our reputation may suffer.

In addition, adverse side effects caused by any therapeutics that may be similar in nature to our product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until our conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;

- the patient eligibility criteria defined in the protocol;

- the size of the study population required for analysis of the trial's primary endpoints;

- the proximity of patients to trial sites;

- the design of the trial;

- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;

- our ability to obtain and maintain patient consents; and

- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic cell transplantation, rather than enroll patients in any future clinical trial.

Even if we can enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Clinical trials are expensive, time-consuming, and difficult to design and implement, and our clinical trial costs may be higher than those for more conventional therapeutic technologies or drug products.

Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies and manufactured on a patient-by-patient basis, we expect that we will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients with relapsed/refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products.

In addition, one of our early-stage product candidates that is currently in preclinical development is for a novel class of injectable biologics. Development of the underlying technology may be affected by unanticipated technical, regulatory, manufacturing, or other problems, among other research and development issues, and the possible insufficiency of funds needed to complete development of this product candidate.

Our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. Depending on the number of patients we ultimately enroll in our trials, and the number of trials we may need to conduct, our overall clinical trial costs may be higher than for more conventional treatments.

Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-out of our manufacturing capabilities. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

Our product candidates are biologics and the process of manufacturing our products is complex, highly regulated, and subject to multiple risks. The manufacture of our product candidates involves complex processes, and, as a result of the complexities, the cost to manufacture biologics in general is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process will be susceptible to product loss or failure due to logistical issues. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. Further, as product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

In addition, the manufacturing process for any products that we may develop is subject to FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If us or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either us or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects.

We rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide it with sufficient quantities of product or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and currently relies on several outside vendors to manufacture supplies and process our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

Although in the future we intend to develop our own manufacturing facility, we also intend to use third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility. We anticipate reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any manufacturers. This approval would require new testing and good manufacturing practices compliance inspections by FDA. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products;

- Our third-party manufacturers might be unable to timely manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;

- Contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;

- Our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our products, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products;

- Our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our products, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products;

- Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practices, or cGMP, current

- good tissue practices, or cGTP, if applicable and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards;

- We may not own, or may not solely own, the intellectual property rights to improvements made by our third-party manufacturers in the manufacturing process for our products;

- Our third-party manufacturers could breach or terminate their agreement with us;

- Raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;

- Our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and

- Our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on us until deficiencies are remedied.

Although our agreements with our CMOs require them to perform according to certain cGMP and, if applicable, cGTP requirements such as those relating to quality control, quality assurance, and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If any of our CMOs cannot successfully manufacture material that conforms to its

specifications and the regulatory requirements of the FDA, EMA, or other comparable foreign authorities, we would be prevented from obtaining regulatory approval for our drug candidates unless and until we engages a substitute CMO that can comply with such requirements, which we may not be able to do. Any such failure by any of our CMOs would significantly impact our ability to develop, obtain regulatory approval for, or market our drug candidates, if approved.

The manufacture of biological drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.

Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints, labor disputes, or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs, and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

Our third-party manufacturers may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing any approved product candidates.

Our manufacturing partners may be unable to successfully increase the manufacturing capacity for our product candidates in a timely or cost-effective manner, or at all, as needed for our development efforts or, if our product candidates are approved, our commercialization efforts. Quality issues may also arise during scale-up activities. If us, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting therapeutic may be delayed or not obtained, which could significantly harm our business.

Cell-based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products.

Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing.

For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, we would have a material adverse effect on our business.

We rely and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will depend upon independent investigators and collaborators to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners, and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs.

We rely and will rely heavily on third parties over the course of our clinical trials, and as a result will have limited control over the clinical investigators and limited visibility into our day-to-day activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on third parties does not relieve it of our regulatory responsibilities. Us and these third parties are required to comply with good clinical practices ("GCP"), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fails to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the applicable GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP, and likely cGTP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

Any agreements governing our relationships with CROs or other contractors with whom we currently engage or may engage in the future may provide those outside contractors with certain rights to terminate a clinical trial under specified circumstances. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

We plan to seek orphan drug status for some or all of our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, 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. After the FDA grants orphan drug designation, the generic identity of the drug 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.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our drug candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We plans to seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products, but exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations.

The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product candidates from applicable regulatory authorities, we will not be able to market and sell those product candidates in those countries or regions and our business could be substantially harmed.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are, and will remain, subject to extensive regulation by the FDA in the United States and by the respective regulatory authorities in other countries where regulations differ. We are not permitted to market our biological product candidates in the United States until we receive the respective approval of a BLA from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory authorities in such countries. The time required to obtain approval, if any, by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials, if approval is obtained at all, and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the type, complexity and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional nonclinical studies or clinical trials. We have limited experience in planning and conducting the clinical trials required for marketing approvals, and we have and expect to continue to rely on third-party CROs to assist us in this process. Obtaining marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP compliance by us or by our CMOs that could result in the candidate not being approved. Moreover, we have not obtained regulatory approval for any drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval.

Our biological product candidates could fail to receive, or could be delayed in receiving, regulatory approval for many reasons, including any one or more of the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for our proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

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

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;

- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate;

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

- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and

- the change of the medical standard of care or the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval.

Even if we were able to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our product candidates for fewer or more limited indications than our requests, may not approve prices we may propose to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials (referred to as "conditional" or "accelerated" approval depending on the jurisdiction), or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our drug candidates.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing, or commercial product distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources, and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all products we develop, it will likely pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist it with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they 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.

Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- 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 clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, 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 products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights, or may use its intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- 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; and collaborators may own or co-own intellectual property covering our products that results from our collaborations with them, and in such cases, we would not have the exclusive right to commercialize such products.

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- our inability to achieve desired efficiencies, synergies or other anticipated benefits from such acquisitions or strategic partnerships;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and

- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake future acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If us, our CROs or our CMOs use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

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

Our internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Although we take reasonable steps to help protect confidential and other sensitive information from unauthorized access or disclosure, we also could be the target of phishing attacks seeking confidential information regarding our employees. Furthermore, while we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some PHI and other PII or confidential information may be transmitted to us by third parties, who may not implement adequate security and privacy measures, and it is possible that laws, rules and regulations relating to privacy, data

protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit PHI and other PII or confidential information to us.

To the extent we or these third parties are found to have violated such laws, rules or regulations or that any disruption or security breach were to result in a loss of, or damage to, our or its third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical 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 or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourself against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing any approved products, these claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities (or the manufacturing processes and facilities of our third-party manufacturer) or our marketing programs, a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Our Risks Relating to Government Regulation

The FDA regulatory approval process is lengthy, time-consuming, and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, adverse event reporting, record keeping, advertising, promotion, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive a Biologics License from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. However, a BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure, potent, and effective for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining regulatory approval to begin a trial, if applicable;
- the availability of financial resources to begin and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an IRB;
- recruiting suitable patients to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol, not complying with GCP, or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites; or
- manufacturing qualified materials under cGMP for use in clinical trials.

Our third-party research institution collaborators may also experience similar difficulties in completing ongoing clinical trials and conducting future clinical trials of product candidates. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes or executive orders will be enacted, or whether any of the FDA's regulations, guidance or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, the next FDA user fee reauthorization package entered stakeholder negotiations in mid-2025, with any agreement to be sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program would need to be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA's review goals for NDAs and other activities supported by user fees assessed against industry.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a

material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Future government shutdowns or slowdowns could also result in delays in our interactions with the SEC and other government agencies, which could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

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

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

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to current Good Manufacturing Practices, or cGMP, and in certain cases Good Tissue Practices ("cGTP"), regulations. As such, us and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and cGTp and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, us and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, cGTP and cGCPs for any clinical trials that we conduct post-approval.

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

- restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process;

- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- withdrawal of the product from the market;
- product recalls;
- warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any of our ongoing clinical trials;
- product seizure or detention or refusal to permit the import or export of products; and
- consent decrees, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we are able to obtain accelerated approval of any of our product candidates, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, and others in the medical community.

Our products may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, and others in the medical community. Several factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;

- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the size of the market for such drug candidate, based on the size of the patient subsets that we are targeting, in their territories for which we gain regulatory approval and have commercial rights;
- the safety of the drug candidate as demonstrated through broad commercial rights;
- the adequacy of supply of our product candidates;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of adequate coverage, reimbursement, and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- support from patient advocacy groups;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement for our product candidates may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any product candidate of ours that receives marketing approval in the future.

Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

We are and will be subject to stringent privacy laws, cybersecurity laws, regulations, policies and contractual obligations related to privacy and security, and changes in such laws, regulations, policies or how they are interpreted or changes in related contractual obligations could adversely affect our business.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, processing, storage and use of personally-identifying information including comprehensive regulatory systems in the U.S. and EU, which, among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations by us or third parties to whom we contract certain types of work (like clinical trials) could result in enforcement action against us or such third parties, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and its contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information or other personal, sensitive, or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal and outside resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In the EU, we may be subject to the General Data Protection Regulation ("GDPR") which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If us or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring we to change the way we uses personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR may also impose additional compliance obligations relating to the transfer of data between us and our subsidiaries or other business partners. For example, the European Court of Justice recently invalidated the EU-U.S. Privacy Shield as a basis for transfers of personal data from the EU to the U.S. and raised questions about the continued validity of one of the primary alternatives to the EU-U.S. Privacy Shield, namely the European Commission's Standard Contractual Clauses. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

While we continue to address the implications of the recent changes to EU data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EU and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change its practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably.

Successful sales of our product candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because our product candidates represent new approaches to treat cancer and other immune-related diseases, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our products. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with applicable laws and regulations of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begins commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in significant regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this

activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending itself or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our relationships with prescribers, purchasers, third-party payors and patients will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of our drug candidates, if approved, we will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct business. Physicians, other health care providers and third-party payors will play a primary role in the recommendation, prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain our business or financial arrangements and relationships through which we market, sell and distribute any products for which we may obtain marketing approval. Restrictions under applicable domestic and foreign health care laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal health care program such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- U.S. federal false claims, false statements and civil monetary penalties laws, including the US False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers;

- the FCPA and other anti-corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials;

- the U.S. federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act," which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Centers for Medicare & Medicaid Services ("CMS"), information related to physician payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as the ownership and investment interests of physicians and their immediate family members. Beginning in 2022, applicable manufacturers are required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year;

- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and/or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and

other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry;

- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs;

- HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act (the "ACA"), among other things, amends the intent requirement of the federal Anti- Kickback Statute and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we is not successful in defending ourself or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from federal health care programs.

Risks Relating to Our Intellectual Property

We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our products or product candidates.

We anticipate that we will file additional patent applications both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when any patents will issue;

- the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;

- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications; or

- whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose.

For biological and pharmaceutical products, claims directed to compositions of matter are generally considered to be the strongest form of intellectual property protection. Such claims are not directed to any particular use of the product, and therefore encompass all uses. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office ("USPTO") or foreign patent offices, or that we issued claims will be considered valid and enforceable by U.S. or foreign courts.

Claims directed to methods of use protect the use of a product for the specified method. This type of claim does not prevent a competitor from making and marketing a product that is identical to the product for a specific use that falls outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method claims. Although off-label prescriptions may infringe or contribute to the infringement of method claims, the practice is common and such infringement is difficult to prevent or prosecute. Many of our issued claims cover methods for making our cell therapy products.

Claims directed to methods of making a product protect the process by which a product is made. This type of claim does not prevent a competitor from marketing a product that is identical to our product, if the competitor's product is made by a process outside the scope of the patented method.

The strength of patents in the biotechnology and pharmaceutical field can be uncertain, and evaluating the scope of such patents involves complex legal and scientific analyses. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates, methods of making our product candidates, or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we are the first to file any patent application related to our product candidates.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

Third-party claims of intellectual property infringement against us or our collaborators may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on us avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, due to changes in U.S. law referred to as patent reform, procedures including inter parties review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, maintaining, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. To date, in addition to the United States, we have filed patent applications in Australia, Brazil, Canada, China, Europe (via European Patent Office), Hong Kong, India, Israel, Japan, Russian Federation, South Korea, Mexico, and Singapore. In addition, the laws of some foreign countries, such as China, Brazil, Russia, and India, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement against importation of infringing products is challenging or legal remedies are insufficient. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, such as China, Brazil, Russia, and India, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding or a declaratory judgment action against us, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put its patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of its licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, or derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of shares of our common stock.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

If us or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which us, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves, both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. 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 our existing patents and patents that we might obtain in the future. For example, in, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc*., the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management and employees.

We may face competition from biosimilars, which may have a material adverse impact on the future commercial prospects of our product candidates.

Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars. The Patient Protection and Affordable Care Act, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"). The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. While certain biosimilar products have been approved by the FDA for use in the United States, none of these have been cell therapy products and none have been interchangeable biosimilars. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidance is expected to be finalized by the FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that the product is "highly similar" to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and, for products administered multiple times, that the biologic and the reference biologic may be switched after one has been

previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own non-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

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

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. 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.

Risks Relating to the Commercialization of Our Product Candidates

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale.

Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger- scale commercial manufacturing process for our product candidates that achieves our objectives for manufacturing capacity and cost of goods. Even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it 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 the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful discovery, development, manufacturing, and sale of biologics is a lengthy, expensive, and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture, and sell our biological product candidates would adversely impact our business and future results of operations.

Even if we are able to commercialize any of our product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or health care reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug and biological products vary widely from country to country. Current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 marketing approval is granted and, in some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and 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 our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the United States, reimbursement varies from payor to payor. Reimbursement agencies in Europe may be more conservative than federal health care programs or private health plans in the United States. For example, a number of cancer drugs are generally covered and paid for in the United States, but have not been approved for reimbursement in certain European countries. A primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payments for particular products. For example, payors may limit coverage to specific drug or biological products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs or biologics for a particular indication. Payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be covered. Additionally, payors may seek to control utilization by imposing prior authorization requirements.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Patients are unlikely to use our products, if they are approved for marketing, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such products. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign 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. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by federal health care programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Further, there have been, and may continue to be, legislative and regulatory proposals at the U.S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare including plans announced by the Trump Administration to reform the U.S. pharmaceutical pricing system significantly through rulemaking and executive orders. In addition, existing legislation aimed at patient affordability in the United States such as the ACA may be repealed or replaced. The continuing efforts of the government, insurance companies, managed care organizations and other third-party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow it to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability.

In some foreign countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability for sales of any of our product candidates that are approved for marketing in that country and our business could be adversely affected.

We have no experience selling, marketing or distributing products and currently have no internal marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently have no sales, marketing or distribution capabilities and have no experience as a company in the sale or marketing of pharmaceutical products. There can be no assurance that we will be able to market and sell our products in the United States or overseas. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Therefore, with respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If so, our success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, such collaborators' strategic interest in the products under development and such collaborators' ability to successfully market and sell any such products.

If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. Further, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

To the extent that we decide not to, or is unable to, enter into collaborative arrangements with respect to the sales and marketing of our products, we may in the future need to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which could be expensive, time-consuming and requiring significant attention of our executive officers to manage. Further, we may not have sufficient resources to allocate to the sales and marketing of our products.

Any failure or delay in the development of sales, marketing and distribution capabilities, through collaboration with one or more third parties or through internal efforts, would adversely impact the commercialization of any of our products that we obtain approval to market. As a result, our future product revenue will suffer and we may incur significant additional losses.

Risks Related to Our Common Stock

Our shares of common stock could be delisted from the Nasdaq Capital Market.

Nasdaq's listing standards provide that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days. On January 29, 2026, we received a Notification Letter from The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market, due to the bid price of the Company's common stock closing below the minimum $1 per share for the 30 consecutive business days prior to the date of the Notification Letter. In accordance with listing rules, we were afforded 180 days, or until July 28, 2026, to regain compliance. On February 26, 2026, Nasdaq informed us that we regained compliance with the minimum bid price requirement.

Although we have regained compliance with the Nasdaq minimum bid price requirement, there is no guarantee that we will remain in compliance with such listing requirements or other listing requirements in the future. Any failure to maintain compliance with continued listing requirements of the Nasdaq Capital Market could result in delisting of our common stock from the Nasdaq

Capital Market and negatively impact our company and holders of our common stock, including by reducing the willingness of investors to hold our common stock because of the resulting decreased price, liquidity and trading of our common stock, limited availability of price quotations and reduced news and analyst coverage. Delisting may adversely impact the perception of our financial condition, cause reputational harm with investors, our employees and parties conducting business with us and limit our access to debt and equity financing

The market price of our common stock is expected to be volatile, and the market price of the common stock may drop.

The market price of our common stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our current and future potential product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- failure of us to achieve the perceived benefits of the Kintara Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our current and future potential product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if we issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our current and future potential product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to IL-6 inhibitor and IL-6R inhibitor product candidates, including with respect to other such products on the market;
- the introduction of technological innovations or new therapies that compete with the products and services of ours; and

- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event resulting from rising interest rates, inflation, global geopolitical conflict, or other macroeconomic conditions could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

Our Articles of Incorporation, as amended, allow for our board of directors to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our board of directors has the authority to issue up to 5,000,000 shares of our preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of additional series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock, or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders. Although we have no present intention to issue any additional shares of preferred stock or to create any additional series of preferred stock, we may issue such shares in the future.

Because we became public by means of a reverse acquisition, we may not be able to attract, or maintain, the attention of brokerage firms.

Because we became public through a "reverse acquisition", securities analysts of brokerage firms may not provide or continue to provide coverage of us since there is little incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any follow-on offerings on our behalf in the future.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

General Risk Factors

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we ultimately compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for our products, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, 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 such products, even if approved.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises, political crises, geopolitical events, or other macroeconomic conditions, which could have a material and adverse effect on our results of operations and financial condition.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates, and uncertainty about economic stability. The Federal Reserve has raised interest rates multiple times in response to concerns about inflation and it may raise them again.

Higher interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more costly, more dilutive, or more difficult to obtain in a timely manner or on favorable terms, if at all. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

We may in the future experience disruptions as a result of such macroeconomic conditions, including delays or difficulties in initiating or expanding clinical trials and manufacturing sufficient quantities of materials. Any one or a combination of these events could have a material and adverse effect on our results of operations and financial condition.

Our articles of incorporation, as amended, allow for our board of directors to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our board of directors has the authority to issue up to 5,000,000 shares of our preferred stock without further stockholder approval. As a result, the board of directors could authorize the issuance of additional series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock, or that is convertible into common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders. Although we have no present intention to issue any additional shares of preferred stock or to create any additional series of preferred stock, we may issue such shares in the future.

Our bylaws designate a state court located in the State of Nevada and, to the extent enforceable, the U.S. federal district courts in Nevada as the exclusive forums for substantially all disputes between us and our stockholders, which will restrict the ability of stockholders to choose the judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director or officer or other employee of ours to us or our stockholders, (iii) any action asserting a claim against us or any director or officer or other employee of ours arising pursuant to any provision of Chapter 78 or Chapter 92A of the NRS or our articles of incorporation or bylaws, or (iv) any action asserting a claim against us or any director or officer or other employee of ours governed by the internal affairs doctrine shall be a state court located within the State of Nevada (or, if no state court located within the State of Nevada has jurisdiction, the federal district court for the District of Nevada). Nothing in the our articles of incorporation or bylaws, would preclude stockholders that assert claims under the Exchange Act from bringing such claims in federal court to the extent the Exchange Act confers exclusive federal jurisdiction over such claims, subject to applicable law of the Securities Act creates concurrent jurisdiction for federal and state courts over all Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Nevada statutes expressly authorize forum selection provisions in bylaws and charters.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

Like many companies, we face significant and persistent cybersecurity risks. The small size of our organization and limited resources could exacerbate these risks. Our business strategy, results of operations, and financial condition have not, to date, been affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property. To effectively prevent, detect, and respond to cybersecurity threats, we maintain a cyber risk management strategy, which is comprised of a wide array of policies, standards, architecture, processes, and governance. Under the guidance and supervision of our Chief Executive Officer, we further limit risk by delegating our information technology and cybersecurity to a leading third-party IT consultant to safeguard our networks. Additionally, as an added layer of security, all of our data is stored on the cloud.

Despite being a small organization, we are committed to maintaining governance and oversight of these risks and to implementing standard operating procedures ("SOPs") and training to help us assess, identify, monitor and respond to these risks. Employees are trained to avoid phishing emails, and our internal controls system is designed to mitigate the risk of payments of fraudulent invoices.

Governance

We aim to incorporate industry best practices for companies of our size and financial strength throughout our cybersecurity program. Our board of directors has ultimate oversight of cybersecurity risk. The Chief Executive Officer reports to our board of directors. Our Chief Executive Officer provides periodic updates to the board of directors on (1) any critical cybersecurity risks; (2) ongoing cybersecurity initiatives and strategies; (3) applicable regulatory requirements; and (4) industry standards. The Chief Executive Officer also notifies the board of directors of any cybersecurity incidents (suspected or actual) and provides updates on the incidents as well as cybersecurity risk mitigation activities as appropriate

Item 2. Properties.

The Company leases approximately 12,199 square feet of office and laboratory space in Tampa, Florida under a lease that is due to expire in March 2028. We believe that our current facilities are adequate to meet our ongoing needs, and that, if we require additional space, we will be able to obtain additional facilities on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may be involved in various disputes and litigation matters that arise in the ordinary course of business. As of the date of this Annual Report, we are not party to any material legal matters or claims other than the following:

On December 12, 2025, we filed an action filed in the Delaware Court of Chancery styled *TuHURA Biosciences, Inc. v. VGXI, Inc. and GeneOne Life Sciences, Inc.*, C.A. No. 2025-1447-NAC (the "Action"). This is an action for breach of contract concerning the defendants' alleged failures to produce GMP-grade plasmid DNA on a timeline that would enable us to fulfill our obligations to the FDA for our clinical trial for its Merkel cell carcinoma treatment and the defendants' alleged fraud in inducing us to enter the contract and subsequently refrain from exercising our rights to terminate the contract and seek cover. The case is in its early stages and discovery has not yet commenced. The complaint was filed on December 12, 2025, and we are waiting for defendants' response to the complaint. We intend to vigorously pursue our claims against the defendants while remaining open to engaging in reasonable and productive settlement discussions.

Item 4. Mine Safety Disclosure.

Not applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "HURA."

Stockholders

As of March 31, 2026, there were approximately 883 registered holders of record of our common stock. This number does not include "street name" or beneficial holders, whose shares are held of record by banks, brokers, financial institutions and other nominees.

Recent Sales of Unregistered Securities; Purchases of Equity Securities by the Issuer or Affiliated Purchaser

None.

Dividend Policy

We currently do not anticipate paying any cash dividends in the foreseeable future. Instead, we anticipate that all of our earnings will be used to provide working capital, to support our operations and to finance the growth and development of our business. Any future determination to declare cash dividends will be made at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant. In addition, if we were to enter into a credit facility in the future, we anticipate that the terms of such facility could limit or prohibit our ability to pay dividends.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth under the heading "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See also "Forward-Looking Statements".

In this section, we discuss our financial condition, changes in financial condition and results of our operations for the year ended December 31, 2025 compared to the year ended December 31, 2024. A discussion of our financial condition, changes in financial condition and results of our operations for the year ended December 31, 2024 compared to the year ended December 31, 2023 can be found under Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," in our Annual Report on Form 10-K for the year ended December 31, 2024 which was filed with the SEC on March 31, 2025 and is available on the SEC's website at www.sec.gov as well as our website at ir.tuhurabio.com. References to "we", "our" and "the Company" refers to Legacy TuHURA for periods prior to the closing of the Kintara Merger, and to TuHURA Biosciences, Inc. (formerly Kintara Therapeutics, Inc.) for all other periods, as the context requires.

Overview

We are a clinical stage immuno-oncology company developing novel technologies designed to overcome primary and acquired resistance to cancer immunotherapies. Our proprietary Immune Fx™ technology platform, or IFx, is an innate immune agonist technology designed to "trick" the body's immune system to attack tumor cells by making tumor cells look like bacteria. Our lead product candidate, IFx2.0, is an innate immune agonist designed to overcome primary resistance to checkpoint inhibitors. In June 2025, we initiated a single randomized placebo-controlled Phase 3 registration trial of IFx-2.0 administered as an adjunctive therapy to Keytruda® (pembrolizumab) in first line treatment for patients with advanced or metastatic Merkel cell carcinoma who are checkpoint inhibitor naïve utilizing the FDA's accelerated approval pathway. In addition to our IFx technology platform, in June 2025 we acquired the rights to TBS-2025, a novel VISTA-inhibiting monoclonal antibody formerly known as KVA1213, through our acquisition of Kineta on June 30, 2025. VISTA (otherwise referred to as *V-domain Ig suppressor of T cell activation*) is an immune checkpoint highly expressed on myeloid cells that is believed to be a strong driver of immunosuppression in the tumor microenvironment and is believed to be a primary mechanism by which leukemic blasts escape immune recognition contributing to low relapse rates and high rates of recurrence in acute myeloid leukemia, or AML. Following our acquisition of Kineta, we are currently planning on investigating TBS-2025 in a randomized Phase 2 trial in combination with a menin inhibitor vs menin inhibitor alone in mutated NPM1 (*mut*NPM1) AML.

To date, we have devoted substantially all of our resources to organizing and staffing, business planning, raising capital, identifying and developing product candidates, enhancing our intellectual property portfolio, undertaking research, conducting preclinical studies and clinical trials, and securing manufacturing for our development programs. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the issuance of capital stock, warrants and convertible notes.

We are not profitable and has incurred significant operating losses in each period since our inception, including net losses of $30.1 million for the year ended December 31, 2025, and $21.7 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $141.2 million. Our operating losses may fluctuate significantly from quarter-to-quarter and year-to-year as a result of several factors, including the timing of our preclinical studies and clinical trials and the expenditures related to other research and development activities. We expect to continue to incur operating losses. We anticipate these losses will increase substantially as it advances our product candidates through preclinical and clinical development, develops additional product candidates and seeks regulatory approvals for our product candidates. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtains regulatory approval for one or more product candidates. In addition, if we obtain marketing approval for any product candidate, we expect to incur pre-commercialization expenses and significant commercialization expenses related to marketing, sales, manufacturing and distribution. We may also incur expenses in connection with the in-licensing of additional product candidates.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial

condition and could force it to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market itself.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2025, we had cash and cash equivalents of $3.6 million. See " *— Liquidity and Capital Resources*" below.

Recent Developments

ATM Offering

On November 3, 2025, the Company and H.C. Wainwright & Co., LLC ("Wainwright") entered into an At-The-Market Offering Agreement (the "Offering Agreement") with respect to an at-the-market offering program under which the Company may sell shares of its common stock having an aggregate offering price of up to $50,000,000 through Wainwright as its sales agent. As of the date of this Annual Report, we have not sold any shares of common stock through the program.

December 2025 Registered Direct Offering

On December 9, 2025, TuHURA Biosciences, Inc. (the "Company") entered into a securities purchase agreement (the "Purchase Agreement") with certain investors (collectively, the "Purchasers"). The Purchase Agreement relates to the sale and issuance in a registered direct offering (such sale and issuance, the "Offering"), by the Company of an aggregate of: (i) 9,462,423 shares of the Company's common stock, (ii) Series A common stock purchase warrants to purchase up to 9,462,423 shares of common stock (the "Series A Warrants"), and (iii) Series B common stock purchase warrants to purchase up to 9,462,423 shares of common stock (the "Series B Warrants", and together with the Series A Warrants, the "Common Warrants").The offering price for each share of common stock and accompanying Series A Warrant and Series B Warrant was $1.65. Each Common Warrant has an exercise price of $1.95 per share and is exercisable beginning six months after the date of issuance.

On the same date, the Company and K&V Investment One LLC ("K&V"), a Purchaser in the Offering, entered into a side letter to the Purchase Agreement (the "Side Letter"), whereby the Company and K&V agreed that, for purposes of K&V's funding requirements under the Purchase Agreement, K&V shall fund (i) with respect to $5 million of K&V's subscription amount, at a date chosen by K&V that is no later than January 30, 2026 (the "Second Closing"), and (ii) with respect to $2 million of K&V's subscription amount, at a date chosen by K&V that is no later than February 27, 2026 (the "Third Closing"). The Company will issue to K&V the shares of common stock and Warrants purchased at each of the Second Closing and Third Closing following receipt of consideration thereof, with such issued Warrants exercisable six months following the date of the Second Closing and the date of the Third Closing, respectively, and expiring on the same date as the Warrants issued to the other Purchasers on December 10, 2025, the first closing date (the "First Closing").

Pursuant to the terms of the Purchase Agreement and the Side Letter, the closing of the Offering occurred in three tranches. At the First Closing, the Company issued an aggregate of 5,219,999 Shares, Series A Warrants to purchase up to an aggregate of 5,219,999 shares of common stock and Series B Warrants to purchase up to an aggregate of 5,219,999 shares of common stock. At the Second Closing, the Company issued to K&V an aggregate of 3,030,303 Shares, Series A Warrants to purchase up to an aggregate of 3,030,303 shares of common stock and Series B Warrants to purchase up to an aggregate of 3,030,303 shares of common stock. At the Third Closing, the Company issued to K&V an aggregate of 1,212,121 Shares, Series A Warrants to purchase up to an aggregate of 1,212,121 shares of common stock and Series B Warrants to purchase up to an aggregate of 1,212,121 shares of common stock. The Series A Warrants will expire five and one-half years from the date of the First Closing and the Series B warrants will expire twenty-four months from the date of the First Closing.

The Offering resulted in gross proceeds to the Company of approximately $8.6 million from the First Closing, approximately $5.0 million from the Second Closing and approximately $2.0 million from the Third Closing, before deducting the placement agents' fees and other offering expenses payable by the Company.

June 2025 Private Placement

On June 2, 2025, the Company and certain accredited investors (the “Private Placement Purchasers”) entered into a securities purchase agreement (the “Securities Purchase Agreement”) pursuant to which the Company agreed to issue to the Private Placement Purchasers, in a private placement (the “Private Placement”), an aggregate of 4,759,309 shares of common stock together with warrants to purchase an equal number of shares of common stock at an exercise price of $3.3125 (the “Private Placement Warrants”), for an aggregate gross offering amount of approximately $12.6 million. The combined effective offering price for each share and accompanying Private Placement Warrant in the Private Placement was $2.65. The Private Placement Warrants have an exercise price per share equal to $3.3125 and will expire on December 31, 2030. The exercise price of the Private Placement Warrants is subject to proportional adjustment for stock splits, reverse stock splits, and similar transactions.

Pursuant to the Securities Purchase Agreement, each Private Placement Purchaser was obligated to purchase such Private Placement Purchaser’s respective investment in the Private Placement in four equal tranches, as follows:

- $2.23 million was purchased on June 2, 2025 (the “Initial Closing”);
- $2.23 million was purchased on June 9, 2025, following the Company's notification to the Private Placement Purchasers that the Food and Drug Administration (FDA) notified the Company that the Company is no longer subject to the partial clinical hold set forth in the FDA's Partial Clinical Hold letter to the Company dated January 24, 2024, with respect to the Company's planned Phase 3 trial of IFx-2.0;
- $2.23 million was purchased on June 24, 2025, following the Company's notification to the Private Placement Purchasers that the Phase 3 trial for IFX-Hu2.0 had been initiated; and
- $2.23 million was purchased on June 30, 2025, following the Company's notification to the Private Placement Purchasers that all material conditions for the closing of the Company's merger transaction with Kineta had been satisfied (other than conditions that could not be satisfied until on or immediately before the closing of the Kineta Merger) and that the Company was prepared to close the Kineta Merger.

In addition to the approximately $8.9 million that was purchased in four equal tranches pursuant to the foregoing milestones, the remaining $3.7 million in the Private Placement (the “Final Tranche Offering Amount”) was required to be purchased and funded by December 31, 2025 by certain Private Placement Purchasers who agreed to invest an aggregate of $4.0 million or more in the Private Placement and who elected to defer the purchase of a portion of such Private Placement Purchaser’s common stock and Private Placement Warrants until such time (the “Deferral Investors”).

On September 5, 2025, each of Deferral Investors and the Company entered into an agreement (the “Final Purchase Agreements”) pursuant to which they agreed to immediately purchase an aggregate of $3.2 million of the Final Tranche Offering Amount in exchange for the Company’s agreement, set forth in a Warrant Amendment Agreement between the Company and each Deferral Investor (the “Warrant Amendment Agreements”), to extend the expiration dates of certain warrants to purchase an aggregate of 1.5 million shares of Company common stock that were issued by the Company’s predecessor in a 2024 private placement of convertible notes (the “2024 Warrants”). An aggregate of $0.5 million remained outstanding in the Final Tranche Offering Amount and was purchased on December 31, 2025. Under the Warrant Amendment Agreements, the expiration dates of the 2024 Warrants was extended to December 31, 2030. The modification of the 2024 Warrants was related to the Private Placement and the incremental fair value relating to the modification has no net equity effect.

Merger with Kineta, Inc.

On June 30, 2025, the Company completed the previously announced acquisition contemplated by the Agreement and Plan of Merger, dated December 11, 2024, and as amended by that certain First Amendment to Agreement and Plan of Merger, dated May 5, 2025 (as amended, the “TuHURA-Kineta Merger Agreement”), by and among the Company, Hura Merger Sub I, Inc., a Delaware corporation and a direct wholly-owned subsidiary of the Company (“Merger Sub I”), Hura Merger Sub II, LLC, a Delaware limited liability company and direct wholly-owned subsidiary of the Company (“Merger Sub II”), Kineta, and Craig Philips, solely in his capacity the representative, agent and attorney-in-fact of the stockholders of Kineta. Pursuant to the terms of the TuHURA-Kineta Merger Agreement, among other things, Merger Sub I (a) merged with and into Kineta (the “First Merger”), with Kineta being the surviving corporation of the First Merger, also known as the “Surviving Entity” and (b) immediately following the First Merger, the Surviving Entity merged with and into Merger Sub II (the “Second Merger”, and together with the First Merger, the “Kineta Merger”), with Merger Sub II being the surviving company of the Second Merger and subsequently changing its name to Kineta, LLC.

Upon completion of the Kineta Merger, pursuant to the terms and conditions of the TuHURA-Kineta Merger Agreement, each share of Kineta common stock, par value $0.001 per share (each, a “Kineta Share”), issued and outstanding immediately prior to the First Merger, was converted into the right to receive 0.185298 shares of the Company’s common stock for an aggregate of

approximately 2,868,169 shares of Company common stock. Also pursuant to the terms and conditions of the TuHURA-Kineta Merger Agreement, each Kineta Share received its pro rata portion of approximately 1,129,880 shares of Company common stock in December 2025, in accordance with the terms of the TuHURA-Kineta Merger Agreement. In addition, each Kineta Share is entitled to the right to its pro rata share of cash consideration received by Kineta pursuant to disposed asset payments related to legacy Kineta assets. Such payments, if any, will be made at a later date and in accordance with the terms of the TuHURA-Kineta Merger Agreement. In each case, in lieu of the issuance of any fractional shares of Company common stock, we will pay an amount equal to the product of (A) such fractional share and (B) $5.7528. As of the date of this Annual Report, all 1,129,880 shares of common stock were issued to the Kineta shareholders and no cash consideration has been received.

Merger with Kintara Therapeutics

On October 18, 2024, we completed the transactions contemplated by the Kintara Merger Agreement. Pursuant to the Kintara Merger Agreement, Merger Sub merged with and into Legacy TuHURA with Legacy TuHURA surviving the merger and becoming Kintara's direct, wholly-owned subsidiary. In connection with the completion of the Kintara Merger, effective at 12:01 a.m. Eastern Time on October 18, 2024, Kintara effected a 1-for-35 reverse stock split of its common stock (the "Reverse Stock Split"). Effective at 12:03 a.m. Eastern Time on October 18, 2024, the Kintara Merger was completed, and effective at 12:04 a.m. Eastern Time on October 18, 2024, Kintara changed its name to "TuHURA Biosciences, Inc."

The Kintara Merger is being accounted for as a reverse recapitalization in accordance with U.S. GAAP, with Kintara treated as the acquired company for financial reporting purposes and TuHURA treated as the accounting acquirer. The Kintara Merger is intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Code.

Subject to the terms and conditions of the Kintara Merger Agreement, at the closing of the Kintara Merger, (a) each then-outstanding share of Legacy TuHURA common stock (other than shares held in treasury and excluding dissenting shares), including shares of Legacy TuHURA common stock issued upon conversion of Legacy TuHURA preferred stock and conversion of all of our convertible promissory notes issued in the Legacy TuHURA's note financing, were converted into the right to receive a number of shares of Kintara common stock (after giving effect to the Reverse Stock Split) based on an exchange ratio of 0.1789 shares of Kintara common stock for each outstanding share of Legacy TuHURA common stock per the Kintara Merger Agreement (the "Exchange Ratio"), and (b) each then-outstanding Legacy TuHURA stock option and warrant that was not exercised immediately prior to the effective time of the Kintara Merger was assumed by Kintara with the number of underlying shares and exercise price being adjusted in accordance with the Exchange Ratio.

Also at the closing of the Kintara Merger, Kintara entered into a Contingent Value Rights Agreement with the Rights Agent (as defined in the Kintara Merger Agreement), pursuant to which holders of Kintara common stock and Kintara common stock warrants, in each case, as of the close of business on the business day immediately prior to the effective time of the Kintara Merger, received one contingent value right (a "CVR") for each outstanding share of Kintara held by such stockholder (or, in the case of the warrants, each share of Kintara common stock for which such warrant is exercisable). Following the achievement of certain prescribed milestones, each CVR received in December 2025 its pro rata portion of 1,539,918 shares of TuHURA common stock.

Components of Our Results of Operations

Revenue

We did not generate any revenue and do not expect to generate any revenue from the sale of products in the near future.

Research and Development Expenses

To date, our research and development expenses have related primarily to the development of IFx-2.0, IFx-3.0 (which we are no longer advancing), TBS-2025, manufacturing, clinical studies, and other early pre-clinical activities related to our portfolio. Research and development expenses are recognized as incurred, and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits;
- external research and development expenses incurred under agreements with contract research organizations ("CROs"), and consultants to conduct our clinical studies;
- laboratory supplies;
- costs related to manufacturing product candidates, including fees paid to third-party manufacturers and raw material suppliers;
- stock-based compensation charges for those individuals involved in research and development efforts; and
- facilities, depreciation, and other allocated expenses, which include direct and allocated expenses for rent.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators and other third-party service providers to assist us with the execution of our clinical trials.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of our product candidates and seek to discover and develop new product candidates.

Due to the inherently unpredictable nature of preclinical and clinical development, we cannot determine with certainty the timing of the initiation, duration or costs of future clinical trials and preclinical studies of product candidates. Clinical and preclinical development timelines, the probability of success and the amount of development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future clinical development costs may vary significantly based on factors such as:

- per-patient trial costs;
- the number of trials required for regulatory approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

Acquisition-related costs

Acquisition-related costs consist of expenses incurred to effect a business combination, including legal, advisory, accounting, and valuation fees and were expensed as incurred.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in our executive, finance, and other administrative functions. Other significant costs include facility related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and insurance costs. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, and, if any product candidates receive marketing approval, commercialization activities.

Other (Expense) Income

Other expense income (expense) consists of grant income from a NIH-funded research grant from Legacy Kintara REM-001, employee retention tax credit for companies affected by the COVID-19 pandemic, loss on settlements related to Kineta former employees separation payments, interest income on our cash and cash equivalents, interest expense on borrowings under our convertible note agreements and 2025 bridge loan, and non-cash changes in the fair value of our derivative liability associated with the make-whole premium on our convertible notes and holdback shares on the Kineta Merger.

Preferred Series A Cash Dividend

Preferred Series A cash dividend represents a cash dividend payable to Valent Technologies, LLC, the holder of our Series A Preferred Stock. Effective September 30, 2014, Kintara filed a Certificate of Designation of Series A Preferred Stock with the Secretary of State of Nevada, pursuant to which, Kintara designated and thereafter issued 278,530 shares of preferred stock as Series A Preferred Stock. The shares of Series A Preferred Stock have a state value of $1.00 per share (the “Series A Stated Value”) and are not convertible into shares of our common stock. The holder of the Series A Preferred Stock is entitled to dividends at the rate of 3% of the Series A Stated Value, payable quarterly in arrears. The dividend has been recorded as a direct increase in accumulated deficit.

Warrant Modification

Warrant modification represents an extension of the exercise period of common stock purchase warrants issued in connection with Legacy TuHURA Series A Preferred Stock for an additional six months, with a new expiry date of February 12, 2025. The warrant modification has been recorded as a direct increase in accumulated deficit.

Results of Operations

Comparisons for the Years Ended December 31, 2025, and December 31, 2024

	Year ended December 31,		Change
	2025	2024	
Operating expenses:			
Research and development	$ 20,532,670	$ 13,335,316	$ 7,197,354
Acquisition-related costs	3,679,618	440,340	3,239,278
General and administrative	7,583,651	3,873,836	3,709,815
Total operating expenses	31,795,939	17,649,492	14,146,447
Loss from operations	(31,795,939)	(17,649,492)	(14,146,447)
Other (expense) income			
Employee retention tax credit	113,574	-	113,574
Grant income	713,508	57,627	655,881
Interest expense	(625,283)	(4,138,301)	3,513,018
Interest income	136,233	361,632	(225,399)
Change in fair value of derivative liability	-	(313,772)	313,772
Change in fair value of Kineta merger holdback shares	1,590,949	-	1,590,949
Loss on Kineta employee separation payments assumed from merger	(185,019)	-	(185,019)
Total other income (expense)	1,743,962	(4,032,814)	5,776,776
Net loss	$ (30,051,977)	$ (21,682,306)	$ (8,369,671)
Series A Preferred cash dividend	(8,356)	(2,089)	(6,267)
Warrant modification	-	(965,177)	965,177
Net loss attributable to common shareholders	$ (30,060,333)	$ (22,649,572)	$ (7,410,761)

Research and Development Expenses. The following table summarizes our research and development expenses by program for the periods presented.

	Year ended December 31,		Change
	2025	2024	
Direct program costs:			
IFx-2.0	$ 8,291,119	$ 7,286,318	$ 1,004,801
TBS-2025	622,796	-	622,796
Preclinical research costs	1,650,881	702,628	948,253
Indirect program costs:			
Personnel and facilities related costs	9,967,874	5,346,370	4,621,504
Total research and development expenses	$ 20,532,670	$ 13,335,316	$ 7,197,354

Research and development expenses were $20.5 million and $13.3 million for the years ended December 31, 2025, and 2024, respectively. The increase of $7.2 million related to the following.

- an increase of approximately $1.0 million due to ongoing clinical development of IFx-2.0;
- an increase of approximately $0.6 million due to ongoing clinical development of TBS-2025;
- an increase of approximately $0.9 million due to preclinical research of IFx-3.0, MDSCs and REM-001; and
- an increase of approximately $4.6 million in facilities, salary and personnel related costs.

Acquisition-related costs. Acquisition related costs were $3.7.million and $0.4 million for the years ended December 31, 2025, and 2024, respectively, and represent costs incurred in relation to the Kineta Merger.

General and Administrative Expenses. General and administrative expenses were $7.4 million and $8.4 million for the years ended December 31, 2025, and 2024, respectively. The increase of $7.0 million was primarily due to increases in non-cash stock compensation expense, and costs associated with being a public company.

Employee Retention Tax Credit. The IRS provided a refundable tax credit for businesses that had employees that were affected during the COVID-19 pandemic. In October 2022, we applied for a credit under this program and we received a credit $0.1 million in 2025.

Grant Income. Grant income was $0.7 million and less than $0.1 million for the years ended December 31, 2025 and 2024, respectively. In October 2024, we assumed the Kintara Health and Human Services grant on REM-001 and received reimbursements for related expenses associated with the grant.

Interest Expense. From December 2023 to September 2024, as part of our private placement financing under which we offered and sold convertible promissory note (the "TuHURA Notes"), we issued convertible notes totaling $31,253,000. The convertible notes included interest at 20% per annum, accretion to maturity date, and amortization of debt discount. Upon the completion of the Kintara Merger, all principal and accrued and unpaid interest and make-whole amounts under the TuHURA Notes automatically converted into shares of our common stock at a conversion price $3.80 per share of our common stock. There was no cash paid for interest in the TuHURA Notes. In October 2024, we entered into a loan agreement with an accredited investor and shareholder for an aggregate principal amount of $3,000,000 incurring interest at 3%, lender warrants, and a loan fee of $180,000.

Interest Income. For the years ended December 31, 2025 and 2024, respectively, interest income was earned on deposits at various banks.

Change in Fair Value of Derivative Liability. For the year ended December 31, 2024, there was a loss of $0.3 million associated with the bifurcated embedded derivative liability related to the make-whole premium on the TuHURA Notes.

Change in Fair Value of Kineta Merger Holdback Shares. For the year ended December 31, 2025, there was a gain of $1.6 million associated with the Kineta Merger holdback shares due to a decrease in the share price in comparison to the date of the closing of the Kineta Merger.

Loss on Kineta Employee Separation Payments. In August 2025 we issued shares to former Kineta employees for separation payments assumed in the Kineta Merger resulting in a loss on settlement of $0.2 million.

Series A Preferred Cash Dividend – The holder of our the Series A Preferred Stock received dividends payable quarterly in arrears, at an annual rate of 3% of the Series A Stated Value.

Deemed Dividend on Warrant Modifications – For the year ended December 31, 2024, there was a $1.0 million deemed dividend due to extending the exercise period on certain of our warrants for an additional six months.

Liquidity and Capital Resources

We have incurred net losses and negative cash flows from operations since our inception and we anticipate that we will continue to incur net losses for the foreseeable future. We incurred net losses of $30.1 million and $21.7 million for the years ended December 31, 2025 and 2024, respectively, and used $27.6 million and $14.7 million of cash from our operating activities for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $141.2 million.

As of December 31, 2025, we had cash and cash equivalents of $3.6 million.

Sources of Liquidity

To date, we have financed our operations principally through the issuance of our capital stock, warrants and debt instruments. Since inception, Legacy TuHURA and the Company have raised approximately $99.7 million in net proceeds through the issuance and sale of capital stock, warrants and debt instruments

Warrant Exercise Notes

On February 12, 2025, four holders (the "Makers") of common stock purchase warrants of the Company made and issued to the Company secured promissory notes (the "Warrant Exercise Notes") in the aggregate principal amount of $3,011,373 as payment of the exercise price of an aggregate of 1,034,836 Warrants held by the Makers. The Makers were comprised of KP Biotech Group, LLC, CA Patel F&F Investments, LLC, Dr. Kiran C. Patel and Donald Wojnowski. Upon the exercise of such warrants, the Company issued to the Makers an aggregate of 1,034,836 shares of common stock. The amounts due under the Warrant Exercise Notes were collected in full in the second quarter of 2025.

Securities Purchase Agreement

On June 2, 2025, the Company and the Private Placement Purchasers entered into the Securities Purchase Agreement pursuant to which the Company agreed to issue and sell to the Private Placement Purchasers, in a private placement, an aggregate of 4,759,309 shares of the Company's common stock, together with the Private Placement Warrants, for an aggregate offering amount of $12.6 million. The combined effective offering price for each share and accompanying Private Placement Warrant in the Private Placement was $2.65.

On December 9, 2025, the Company entered into the Purchase Agreement with the "Purchasers. The Purchase Agreement relates to the sale and issuance in a registered direct offering by the Company of an aggregate of: (i) 9,462,423 shares of the Company's common stock, (ii) Series A Warrants to purchase up to 9,462,423 shares of common stock, and (iii) Series B Warrants to purchase up to 9,462,423 shares of common stock. The offering price for each share of common stock and accompanying Series A Warrant and Series B Warrant was $1.65. Each Common Warrant has an exercise price of $1.95 per share and is exercisable beginning six months after the date of issuance.

Cash Flows

The following table sets forth a summary of the net cash flow activity for the years ended December 31, 2025 and 2024, respectively:

	Year Ended December 31,	
	2025	**2024**
Net cash provided by (used in):		
Operating activities	$ (27,629,150)	$ (14,728,138)
Investing activities	(1,335,361)	(6,052,409)
Financing activities	19,927,282	29,772,693
Net increase (decrease) in cash	$ (9,037,229)	$ 8,992,146

Operating Activities

For the year ended December 31, 2025, net cash used in operating activities was $27.6 million, which primarily consisted of a net loss of $30.1 million, a change in net operating assets and liabilities of $3.1 million, and net non-cash charges of $5.6 million. The net non-cash charges were primarily related to a $1.6 million change in fair value of holdback shares, amortization of debt discount of $0.5 million, depreciation and amortization expense of $0.1 million, and stock-based compensation of $6.4 million. The $3.1 million net change in operating assets and liabilities is primarily due to decreases in accounts payable and accrued expenses of approximately $3.8 million due to timing of invoices and vendor payments, and an increase in current and non-current assets of approximately $0.6 million.

For the year ended December 31, 2024, net cash used in operating activities was $14.7 million, which primarily consisted of a net loss of $21.7 million, a change in net operating assets and liabilities of $3.3 million, and net non-cash charges of $3.7 million. The net non-cash charges were primarily related to a $0.3 million change in fair value of derivative liability, amortization of debt discount of $1.3 million, depreciation and amortization expense of $0.1 million, and stock-based compensation of $2.0 million. The $3.3 million net change in operating assets and liabilities is primarily due to increases in accounts payable and accrued expenses of approximately $3.6 million due to timing of invoices and vendor payments, and a decrease in current and non-current assets of approximately $0.3 million.

Investing Activities

For the year ended December 31, 2025, net cash used in investing activities was $1.3 million, which consisted of purchases of property and equipment and deposits and exclusivity payments in connection with the Kineta Merger.

For the year ended December 31, 2024, net cash used in investing activities was $6.1 million, which consisted of purchases of property and equipment and deposits and exclusivity payments in connection with the Kineta Merger.

Financing Activities

For the year ended December 31, 2025, net cash provided by financing activities was $20.0 million, which consisted of $18.4 million net proceeds from the Private Placement in June 2025 and the Offering in December 2025, $3.0 million gross proceeds from the TuHURA bridge loan financing, and $3.6 million proceeds from the Legacy TuHURA warrants exercises, offset by $1.1 million payment in merger transaction costs and net liabilities attributable to Kintara, $3.2 million payment of the TuHURA bridge loan financing, $0.5 million payment of notes payable to former Kineta employees for separation payments assumed from the merger, and $0.4 million payment of Kineta debt assumed from the Kineta Merger.

For the year ended December 31, 2024, net cash provided by financing activities was $29.8 million, which consisted of $27.5 million net proceeds from convertible notes issued as part of the TuHURA Note Financing, $4.7 million net proceeds from the Legacy TuHURA private placement in July 2024, and $2.0 million proceeds from stock options and warrants exercises, offset by $4.4 million payment in merger transaction costs and net liabilities attributable to Kintara.

Funding Requirements

We expect to incur costs associated with operating as a public company. In addition, we anticipate that we will need substantial additional funding in connection with our development programs and continuing operations. We believe that our existing cash and cash equivalents, together with the ATM and the proceeds received in the Offering, will be sufficient to meet our anticipated cash requirements through the second quarter and into the third quarter of 2026.

Our forecast of the period through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Management based projections of operating capital requirements on our current operating plan, which includes several assumptions that may prove to be incorrect, and we may deplete our available capital resources sooner than management expects. Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of drug discovery, preclinical studies and clinical trials of IFx-2.0, TBS-2025, and any other future product candidates;
- the costs associated with hiring additional personnel and consultants as our preclinical and clinical activities increase;
- the outcome, timing and costs of seeking regulatory approvals;
- the cost of manufacturing IFx-2.0, TBS-2025, and future product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the emergence of competing therapies and other adverse market developments;
- the ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our capital requirements, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may need to relinquish valuable rights to our product candidates, future revenue streams or

research programs or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings as and 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 our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in Note 2 of our consolidated financial statements for the year ended December 31, 2025, contained in Item 8 in this Annual Report, we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. we estimate the fair value of equity awards using the Black-Scholes option pricing model and recognizes forfeitures as they occur. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Note 2 of our financial statements for information concerning certain of the specific assumptions we use in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted.

Kineta Acquisition and Valuation of Intangible Assets

On June 30, 2025 we completed the Kineta Merger contemplated by the TuHURA-Kineta Merger Agreement, pursuant to which the Company acquired Kineta in a cash and stock transaction through a series of merger transactions, with Kineta surviving the mergers as a wholly-owned subsidiary of ours.

Upon completion of the Kineta Merger, pursuant to the terms and conditions of the TuHURA-Kineta Merger Agreement, each Kineta Share issued and outstanding immediately prior to the First Merger, was converted into the right to receive 0.185298 shares of our common stock for an aggregate of approximately 2,868,169 shares of our common stock. Also pursuant to the terms and conditions of the TuHURA-Kineta Merger Agreement, each Kineta Share received its pro rata portion of approximately 1,129,880 shares of our common stock in December 2025, in accordance with the terms of the TuHURA-Kineta Merger Agreement. In addition, each Kineta Share is entitled to the right to its pro rata share of cash consideration received by Kineta pursuant to disposed asset payments related to legacy Kineta assets. Such payments, if any, will be made at a later date and in accordance with the terms of the TuHURA-Kineta Merger Agreement. In each case, in lieu of the issuance of any fractional shares of our common stock, we will pay an amount equal to the product of (A) such fractional share and (B) $5.7528.

The estimated fair value of the aggregate share component of the Kineta Merger was calculated using the closing stock price on the date of the Kineta Merger.

We recognized in-process research and development ("IPR&D") in connection with the acquisition. The preliminary fair value of the acquired IPR&D intangible assets was determined based on the market capitalization of Kineta, as previously traded on the Nasdaq capital market.

Goodwill and other intangible assets comprised of IPR&D on our balance sheet as of December 31, 2025 were in connection with the Kineta Merger.

In a business combination, the fair value of acquired IPR&D is capitalized and accounted for as indefinite-lived intangible assets, and not amortized until the underlying project receives regulatory approval, at which point the intangible assets will be accounted for as definite-lived intangible assets or discontinued. If discontinued, the intangible assets will be written off. R&D costs incurred after the acquisition are expensed as incurred.

We will engage a third-party valuation firm to assist us with the valuation of the IPR&D. The valuation of our acquired IPR&D has significant measurement uncertainty given the lack of historical data on which to base assumptions. Assumptions are difficult to make accurately and were mainly derived from life science studies, industry data, and peer company information that our management believes represent appropriate comparable data.

We test indefinite-lived intangible assets for impairment by first assessing qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If we conclude it is more likely than not that the fair value is less than its carrying amount, a quantitative impairment test is performed.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our financial statements.

Off-Balance Sheet Arrangements

During the periods presented, we do not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risks and inflation risks. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We deposit our cash in financial institutions that we believe has high credit quality and have not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Interest Rate Risk

Our cash consists of cash in readily-available checking accounts. We may also invest in short-term money market fund investments. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In

addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management has evaluated, with the participation of the Chief Executive Officer and the Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on this evaluation, our Chief Executive Officer and the Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2025.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria set forth in "Internal Control – Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

For so long as we qualify as a non-accelerated filer, our independent registered public accounting firm is not required to issue an attestation report on our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

Other than changes due to the Kineta Merger, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) None.

(b) During the year ended December 31, 2025, no directors or "officers" (as defined in Rule 16a-1(f) under the Exchange Act) of our Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" and/or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

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 will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2026 annual meeting of stockholders or an amendment to this Form 10-K, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2025.

Our board of directors has adopted a Code of Ethics and Conduct that applies to our executive officers, as well as to the members of our board of directors and our other officers and employees (the "Code of Conduct"). The Code of Conduct is available on our website at https://www.ir.tuhurabio.com/corporate-governance/governance-documents. We intend to satisfy the amendment and waiver disclosure requirements under applicable securities regulations by posting any amendments of, or waivers to, the Code of Ethics and Conduct on our website.

We have adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of securities of the Company by directors, officers, and employees that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and applicable Nasdaq listing standards. Our insider trading policy states, among other things, that our directors, officers, and employees are prohibited from trading in such securities while in possession of material, nonpublic information. In addition, with regard to trading in our own securities, it is our policy to comply with the federal securities laws and the applicable exchange listing requirements. The foregoing summary of our insider trading policies and procedures does not purport to be complete and is qualified by reference to our insider trading policy attached hereto as Exhibit 19.1 and incorporated herein.

Item 11. Executive Compensation.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2026 annual meeting of stockholders or an amendment to this Form 10-K, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management Related Stockholder Matters.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2026 annual meeting of stockholders or an amendment to this Form 10-K, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2026 annual meeting of stockholders or an amendment to this Form 10-K, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

The information required by this Item will be included in and is hereby incorporated by reference from our definitive proxy statement relating to our 2026 annual meeting of stockholders or an amendment to this Form 10-K, which we intend to file within 120 days after the end of our fiscal year ended December 31, 2025.

Part IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this Annual Report on Form 10-K:

(a)(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.

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(a)(3) Exhibits

The following is a list of exhibits filed (or incorporated by reference herein) as part of this Annual Report on Form 10-K.

Exhibit Number	Description
1.1	At-the-Market Offering Agreement, dated as of November 3, 2025, between TuHURA Biosciences, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.2 to TuHURA Biosciences, Inc.'s Registration Statement on Form S-3 filed with the SEC on November 3, 2025 (Registration No. 333-291239)
2.1††	Agreement and Plan of Merger, dated as of December 11, 2024, by and among TuHURA Biosciences, Inc., Kineta, Inc., Hura Merger Sub I, Inc., Hura Merger Sub II, LLC and Craig Philips (incorporated by reference to Exhibit 2.1 of TuHURA's Current Report on Form 8-K filed with the SEC on December 12, 2024)
2.2††	Agreement and Plan of Merger, dated as of April 2, 2024, by and among Kintara Therapeutics, Inc., Kayak Mergeco, Inc., and TuHURA Biosciences, Inc., as amended (incorporated by reference to Exhibit 2.1 of TuHURA's (f/k/a Kintara Therapeutics, Inc.) Current Report on Form 8-K filed with the SEC on April 3, 2024)
3.1	Articles of Incorporation of TuHURA Biosciences, Inc. (f/k/a Kintara Therapeutics, Inc.), as amended (incorporated by reference to Exhibit 3.1 to TuHURA Biosciences, Inc.'s Registration Statement on Form S-1 filed with the SEC on August 12, 2025 (Registration No. 333-289532)
3.2	Amended and Restated Bylaws of TuHURA Biosciences, Inc. (f/k/a Kintara Therapeutics, Inc.) (incorporated by reference to Exhibit 3.1 to TuHURA's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2022)
4.1	Form of TuHURA Biosciences, Inc. (f/k/a Morphogenesis, Inc.) Common Stock Purchase Warrant issued in Series A Preferred Offering (incorporated by reference to Exhibit 4.12 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))
4.2	Form of TuHURA Biosciences, Inc. (f/k/a Morphogenesis, Inc.) Common Stock Purchase Warrant, dated June 1, 2019, issued for advisory services (incorporated by reference to Exhibit 4.13 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))
4.3	Form of TuHURA Biosciences, Inc. (f/k/a Morphogenesis, Inc.) Common Stock Purchase Warrant issued in Note Conversion Transaction (incorporated by reference to Exhibit 4.15 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))
4.4	Form of TuHURA Biosciences, Inc. (f/k/a Morphogenesis, Inc.) Common Stock Purchase Warrant issued in Series B Preferred Stock Offering (incorporated by reference to Exhibit 4.16 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))

4.5	Form of TuHURA Biosciences, Inc. Common Stock Warrant issued in TuHURA Note Financing (incorporated by reference to Exhibit 4.17 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))
4.6	Form of Pre-Funded Warrant Certificate (incorporated by reference to Exhibit 4.2 of Amendment No. 1 to TuHURA Biosciences, Inc.'s (f/k/a Kintara Therapeutics, Inc.) Current Report on Form 8-K/A filed with the SEC on August 15, 2019)
4.7	Form of Investor Warrant (incorporated by reference to Exhibit 4.1 to TuHURA Biosciences, Inc.'s (f/k/a Kintara Therapeutics, Inc.) Current Report on Form 8-K filed with the SEC on April 13, 2022)
4.8	Form of Investor Warrant (incorporated by reference to Exhibit 4.1 to TuHURA Biosciences, Inc.'s (f/k/a Kintara Therapeutics, Inc.) Current Report on Form 8-K filed with the SEC on April 13, 2022)
4.9	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to TuHURA Biosciences, Inc.'s (f/k/a Kintara Therapeutics, Inc.) Current Report on Form 8-K filed with the SEC on April 13, 2022)
4.10	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to TuHURA Biosciences, Inc.'s Current Report on Form 8-K filed with the SEC on June 6, 2025)
4.11	Form of Common Stock Purchase Warrant issued pursuant to Secured Promissory Note and Loan Agreement (incorporated by reference to Exhibit 10.2 to TuHURA Biosciences, Inc.'s Form 8-K filed with the SEC on October 31, 2025)
4.12	Form of Indenture (incorporated by reference to Exhibit 4.19 to TuHURA Biosciences, Inc.'s Registration Statement on Form S-3 filed with the SEC on November 3, 2025 (Registration No. 333-291239))
4.13	Form of Subordinated Indenture (incorporated by reference to Exhibit 4.20 to TuHURA Biosciences, Inc.'s Registration Statement on Form S-3 filed with the SEC on November 3, 2025 (Registration No. 333-291239))
4.14	Form of Series A Purchase Warrant (incorporated by reference to Exhibit 4.1 to TuHURA Biosciences, Inc.'s Form 8-K filed with the SEC on December 10, 2025)
4.15	Form of Series B Purchase Warrant (incorporated by reference to Exhibit 4.2 to TuHURA Biosciences, Inc.'s Form 8-K filed with the SEC on December 10, 2025)
4.16	Form of Placement Warrant (incorporated by reference to Exhibit 4.3 to TuHURA Biosciences, Inc.'s Form 8-K filed with the SEC on December 10, 2025)
4.17*	Description of the Registrant's Securities
10.1#	Form of Indemnification Agreement by and between TuHURA Biosciences, Inc and each of its directors and executive officers (incorporated by reference to Exhibit 10.2 of TuHURA's Current Report on Form 8-K filed with the SEC on October 21, 2024)

10.2#	TuHURA Biosciences, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 of TuHURA Biosciences, Inc. (f/k/a Kintara Therapeutics, Inc.) Current Report on Form 8-K filed with the SEC on October 21, 2024)
10.3#	Second Amended and Restated Employment Agreement, dated March 29, 2024, between TuHURA Biosciences, Inc. and Dan Dearborn (incorporated by reference to Exhibit 10.34 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))
10.4#	Second Amended and Restated Employment Agreement, dated March 29, 2024, between TuHURA Biosciences, Inc. and James Bianco, M.D (incorporated by reference to Exhibit 10.35 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))
10.5†	Exclusive License Agreement, dated March 29, 2019, between Morphogenesis, Inc. and H. Lee Moffitt Cancer Center and Research Institute, Inc., as amended (incorporated by reference to Exhibit 10.37 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))
10.6†	Exclusive License Agreement, dated April 23, 2021, between Morphogenesis, Inc. and H. Lee Moffitt Cancer Center and Research Institute, Inc., as amended (incorporated by reference to Exhibit 10.38 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368)
10.7†	Restated and Amended Exclusive License Agreement, effective September 7, 2022, between TuHURA Biopharma, Inc. and West Virginia Research Corporation (incorporated by reference to Exhibit 10.39 to the Registration Statement on Form S-4 filed on May 13, 2024 (Registration No. 333-279368))
10.8#	Form of TuHURA Biosciences, Inc. Stock Option Agreement under the TuHURA Biosciences, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the SEC on November 15, 2024)
10.9#	TuHURA Biosciences, Inc. 2025 Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.18 to TuHURA Biosciences, Inc.'s Form 10-K filed with the SEC on March 31, 2025)
10.10	Form of Securities Purchase Agreement, dated as of June 2, 2025, by and among TuHURA Biosciences, Inc. and the investors named therein (incorporated by reference to Exhibit 10.1 to TuHURA Biosciences, Inc.'s Form 8-K filed with the SEC on June 6, 2025)
10.11	Form of Warrant Amendment Agreement, dated as of September 5, 2025, between TuHURA Biosciences, Inc. and the holders named therein (incorporated by reference to Exhibit 10.2 to TuHURA Biosciences, Inc.'s Form 8-K filed with the SEC on September 11, 2025)
10.12††	Form of Securities Purchase Agreement, dated as of December 9, 2025, by and among the Company and the Purchasers named therein (incorporated by reference to Exhibit 10.1 to TuHURA Bioscience, Inc.'s Form 8-K filed with the SEC on December 10, 2025)
10.13	Side Letter Agreement, dated December 9, 2025, between TuHURA Biosciences, Inc. and K&V Investment One LLC (incorporated by reference to Exhibit 10.2 to TuHURA Biosciences, Inc.'s Form 8-K filed with the SEC on December 10, 2025)
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to TuHURA Biosciences, Inc. Form 10-K filed with the SEC on March 31, 2025)
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to TuHURA Biosciences, Inc's Current Report on Form S-1 filed with the SEC on August 12, 2025)
23.1*	Consent of Cherry Bekaert LLP, independent registered public accounting firm.

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.
31.2 *	Certification of Principal Financial 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.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	TuHURA Biosciences, Inc. Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to TuHURA Biosciences, Inc.'s Form 10-K filed March 31, 2025)
101.INS	XBRL Instance Document
101.SCH	SBRL Schema Document
101.CAL	Calculation Linkbase Document
101.DEF	Definition Linkbase Document
101.LAB	XBRL Label Linkbase Document
101.PRE	XBRL Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

† Confidential treatment is requested for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Exchange Act. In accordance with Rule 24b-2, these confidential portions have been omitted from this exhibit and filed separately with the Securities and Exchange Commission.
†† Schedule has been omitted pursuant to Item 601(a)(5) of Regulation S-K. TuHURA hereby undertakes to furnish copies of any of the omitted schedules upon request by the Securities and Exchange Commission.
# Indicates a management contract or any compensatory plan, contract or arrangement.
* Filed herewith.
** This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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 report to be signed on its behalf by the undersigned, thereunto duly authorized.

TUHURA BIOSCIENCES, INC.

Dated: March 31, 2026

By: /s/ James A. Bianco
Name: James A. Bianco, M.D.
Title: President and Chief Executive Officer

KNOW ALL THESE PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James A. Bianco, M.D. and Dan Dearborn and each of them, jointly and severally, his attorneys-in-fact, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each said attorneys-in-fact or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report 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/ James A. Bianco James A. Bianco, M.D. Chief Executive Officer	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2026
/s/ Dan Dearborn Dan Dearborn Chief Financial Officer	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2026
/s/ James Manuso James Manuso, Ph.D.	Director	March 31, 2026
/s/ Alan List Alan List, M.D.	Director	March 31, 2026
/s/ George Ng George Ng	Director	March 31, 2026
/s/ Robert Hoffman Robert Hoffman	Director	March 31, 2026
/s/ Craig Tendler Craig Tendler, M.D.	Director	March 31, 2026

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

TuHURA Biosciences, Inc. and Subsidiaries

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Stockholders and the Board of Directors
TuHURA Biosciences, Inc.
Tampa, Florida

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TuHURA Biosciences, Inc. (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, stockholders' (deficit) equity, and cash flows for the years then ended, and the related notes to the consolidated financial statements (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, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt of the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the consolidated financial statements, the Company has incurred net losses since its inception which has resulted in a cumulative deficit as of December 31, 2025 that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3.

Basis for Opinion

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

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

Our 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 our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

Critical Audit Matter Description

As discussed in Note 5 to the consolidated financial statements, during the year ended December 31, 2025, the Company completed the merger of Kineta, Inc., which was accounted for as a business combination. Accounting for the business combination required management to make significant judgements and estimates, particularly related to the determination of the fair values of the acquired intangible assets. We identified the accounting for the business combination as a critical audit matter because the valuation of the acquired intangible assets involved especially complex and subjective judgements, including the use of significant assumptions.

As a result, a high degree of auditor judgment was required in performing audit procedures to evaluate the reasonableness of management's estimates. Changes in these estimates can have a material effect on the amount of intangible assets and goodwill recognized in the business combination.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accounting for the business combination included, among others:

- We obtained an understanding of the transaction and evaluated whether the merger was appropriately accounted for as a business combination.
- We assessed the competence and objectivity of management's valuation specialists involved in the fair value measurements.
- With the assistance of our valuation specialists, we evaluated the valuation methodologies used to estimate the fair values of the identifiable intangible assets and tested the significant assumptions used by comparing them to relevant and reliabile information.
- We evaluated the reasonableness of the resulting purchase price allocation and assessed whether the related disclosures in the consolidated financial statements were appropriate and complete.

/s/ *Cherry Bekaert LLP*

We have served as the Company's auditor since 2018.

Tampa, Florida
March 31, 2026

TUHURA BIOSCIENCES, INC AND SUBSIDIARIES
Consolidated balance sheets
December 31, 2025, and 2024

	December 31, 2025	December 31, 2024
Assets		
Current Assets:		
Cash and cash equivalents	$ 3,619,949	$ 12,657,178
Deposits, planned business acquisition (note 1)	-	5,994,503
Stock subscription receivable	500,000	-
Other current assets	501,187	958,708
Total Current Assets	4,621,136	19,610,389
Property and equipment, net	300,639	123,366
Operating right-of-use assets	384,530	199,160
Other noncurrent assets	33,769	33,769
Goodwill	10,738,082	-
In-process research and development	11,275,000	-
Total Assets	$ 27,353,156	$ 19,966,684
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 5,522,887	$ 5,170,166
Kineta severance promissory notes	197,354	-
Lease liabilities, current	199,041	159,844
Total Current Liabilities	5,919,282	5,330,010
Long-term Liabilities:		
Lease liability, long term	303,627	42,698
Deferred tax liability	197,919	-
Total Liabilities	6,420,828	5,372,708
Commitments and contingencies (note 14)		
Stockholders' Equity:		
Preferred Stock Series A; $1.00 par value, 278,530 shares outstanding as of December 31, 2025 and 2024	278,530	278,530
Common stock, $0.001 par value, 200,000,000 and 75,000,000 shares authorized as of December 31, 2025 and 2024; 59,336,104 and 12,167,679 shares issued and outstanding as of December 31, 2025 and 2024.	59,336	42,324
Additional paid in capital	161,779,364	125,397,691
Accumulated deficit	(141,184,902)	(111,124,569)
Total Stockholders' Equity	20,932,328	14,593,976
Total Liabilities and Stockholders' Equity	$ 27,353,156	$ 19,966,684

TUHURA BIOSCIENCES, INC AND SUBSIDIARIES

Consolidated statements of operations

For the years ended December 31, 2025, and 2024

	Year Ended December 31,	
	2025	2024
Research and development expenses	$ 20,532,670	$ 13,335,316
Acquisition-related costs (note 5)	3,679,618	440,340
General and administrative expenses	7,583,651	3,873,836
Operating Loss	(31,795,939)	(17,649,492)
Other (Expense) Income:		
Employee Retention Tax Credit	113,574	-
Grant income	713,508	57,627
Interest expense	(625,283)	(4,138,301)
Interest income	136,233	361,632
Change in fair value of derivative liability	-	(313,772)
Change in fair value of Kineta merger holdback shares	1,590,949	-
Loss on Kineta employee separation payments assumed from merger	(185,019)	-
Total Other Income (Expense)	1,743,962	(4,032,814)
Net Loss	$ (30,051,977)	$ (21,682,306)
Series A Preferred cash dividend	(8,356)	(2,089)
Deemed dividend on warrant modifications	-	(965,177)
Net Loss attributable to common stockholders	$ (30,060,333)	$ (22,649,572)
Net Loss per share, basic and diluted	$ (0.63)	$ (1.21)
Weighted-average shares outstanding, basic and diluted	47,927,196	18,662,690

TUHURA BIOSCIENCES, INC AND SUBSIDIARIES
Consolidated statements of stockholders' equity (deficit)
For the years ended December 31, 2025, and 2024

	Preferred Stock		Common Stock		Additional Paid in	Accumulated Equity	Total Stockholders' Equity
	Shares	Dollars	Shares	Dollars	Capital	(Deficit)	(Deficit)
Balances at January 1, 2025	278,530	$ 278,530	42,323,759	$ 42,324	$ 125,397,691	$ (111,124,569)	$ 14,593,976
Issuance of common shares for warrants exercised	-	-	1,208,104	1,208	3,619,449	-	3,620,657
Stock options exercised, cashless	-	-	154,387	154	(154)	-	-
Issuance of common shares in PIPE, net of issuance costs	-	-	4,759,309	4,759	11,212,131	-	11,216,890
Issuance of common shares in RDO, net of issuance costs	-	-	5,219,999	5,220	7,241,996	-	7,247,216
Issuance of common shares for Kineta merger	-	-	3,997,761	3,998	7,250,735	-	7,254,733
Issuance of common shares to former Kineta employees for separation payments	-	-	133,233	133	332,902	-	333,035
Vesting of RSU shares	-	-	57	-	-	-	-
Release of shares to Kintara contingent value rights holders	-	-	1,539,495	1,540	(1,540)	-	-
Stock compensation expense	-	-	-	-	6,424,730	-	6,424,730
Fair value of warrants associated with bridge loan	-	-	-	-	301,424	-	301,424
Series A Preferred Stock cash dividend	-	-	-	-	-	(8,356)	(8,356)
Net loss	-	-	-	-	-	(30,051,977)	(30,051,977)
Balances at December 31, 2025	278,530	$ 278,530	59,336,104	$ 59,336	$ 161,779,364	$ (141,184,902)	$ 20,932,328

The accompanying notes to the consolidated financial statements are an integral part of this statement.

TUHURA BIOSCIENCES, INC AND SUBSIDIARIES

Consolidated statements of stockholders' equity (deficit) continued

For the years ended December 31, 2025, and 2024

	Preferred Stock		Common Stock		Additional Paid in	Accumulated Equity	Total Stockholders' Equity
	Shares	Dollars	Shares	Dollars	Capital	(Deficit)	(Deficit)
Balances at January 1, 2024	16,912,843	$ 16,913	12,167,679	$ 12,168	$ 86,887,170	$ (88,474,997)	$ (1,558,746)
Conversion of preferred stock to common stock	(16,912,843)	(16,913)	16,912,843	16,913	-	-	-
Issuance of common stock upon settlement of convertible notes	-	-	9,866,756	9,867	24,879,782	-	24,889,649
Reclassification of the derivative liability associated with the convertible notes make-whole premium	-	-	-	-	2,853,000	-	2,853,000
Common stock and preferred stock (assumed from merger) to Kintara shareholders in reverse recapitalization	278,530	278,530	1,842,920	1,843	(1,627,285)	-	(1,346,912)
Transaction costs in connection with the reverse recapitalization	-	-	-	-	(4,129,663)	-	(4,129,663)
Issuance of common shares, net of offering costs	-	-	717,322	717	4,599,283	-	4,600,000
Issuance of common shares for equity issuance and convertible notes for placement agent fees	-	-	77,798	78	443,482	-	443,560
Issuance of common shares for warrants exercised	-	-	646,580	647	1,944,118	-	1,944,765
Stock options exercised, cash and cashless	-	-	91,862	92	103,908	-	104,000
Stock compensation expense	-	-	-	-	1,958,663	-	1,958,663
Fair value of warrants associated with convertible notes payable	-	-	-	-	6,520,056	-	6,520,056
Deemed dividend on warrant modifications	-	-	-	-	965,177	(965,177)	-
Series A Preferred Stock cash dividend	-	-	-	-	-	(2,089)	(2,089)
Net loss	-	-	-	-	-	(21,682,306)	(21,682,306)
Balances at December 31, 2024	278,530	$ 278,530	42,323,759	$ 42,324	$ 125,397,691	$ (111,124,569)	$ 14,593,976

TUHURA BIOSCIENCES, INC AND SUBSIDIARIES
Consolidated statements of cash flows
For the years ended December 31, 2025, and 2024

	Years ended	
	December 31, 2025	December 31, 2024
Cash flows from Operating activities:		
Net loss	$ (30,051,977)	$ (21,682,306)
Adjustments to reconcile net loss to cash used in operating activities:		
Stock compensation expense	6,424,730	1,958,663
Depreciation and amortization	71,265	116,710
Amortization of debt discount	481,424	1,278,424
Loss on share issuance to Kineta separation payments	185,019	-
Change in fair value of holdback shares	(1,590,948)	-
Change in fair value of derivative liability	-	313,772
Changes in operating assets and liabilities:		
Other current assets	457,523	(464,938)
Other noncurrent assets	154,998	106,613
Accounts payable and accrued expenses	(3,761,184)	3,644,924
Net cash flows from operating activities	(27,629,150)	(14,728,138)
Cash flows from investing activities:		
Cash paid for Kineta acquisition, net of assumed cash	(1,259,278)	(5,994,503)
Purchase of property and equipment	(76,083)	(57,906)
Net cash flows from investing activities	(1,335,361)	(6,052,409)
Cash flows from financing activities:		
Series A Preferred dividend	(8,356)	-
Repayment of assumed Kineta indeptedness	(434,000)	-
Payments made on Kineta severance promissory notes	(394,709)	-
Payments on equipment lease	(54,315)	-
Proceeds from convertible notes payable	-	28,568,000
Proceeds from bridge note	3,000,000	-
Payment of bridge note	(1,500,000)	-
Proceeds from issuance of common stock	18,303,312	5,000,000
Proceeds from stock options exercised	-	104,000
Proceeds from warrants exercised	3,620,657	1,944,765
Payment of offering costs associated with issuance of common stock	(1,555,307)	(300,000)
Payment of merger transaction costs	(500,000)	(3,629,663)
Payment of debt issuance costs	-	(1,117,497)
Payment of net liabilities assumed in reverse recapitalization	(550,000)	(796,912)
Net cash flows from financing activities	19,927,282	29,772,693
Net change in cash and cash equivalents	(9,037,229)	8,992,146
Cash and cash equivalents at the beginning of the year	12,657,178	3,665,032
Cash and cash equivalents at the end of the year	$ 3,619,949	$ 12,657,178
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 59,364	$ -
Supplemental non-cash activity		
Right-of-use asset recognized in exchange for operating lease obligations	$ 340,368	$ 318,722
Right-of-use asset recognized in exchange for finance lease obligations	172,453	-
Deferred offering costs not yet paid	463,903	-
Consideration for Kineta acquisition issued in shares	8,915,661	-
Net liabilities assumed in reverse recapitalization not yet paid	-	550,000
Merger transaction costs not yet paid	-	500,000
Derivative liability associated with make-whole premium	-	2,402,228
Warrants issued recorded as a debt discount	301,424	6,520,056
Deemed dividend on warrant modifications	-	965,177
Shares issued for placement agent fees	-	443,560
Contingent value rights associated with Kintara merger	-	5,127,927
Warrants issued to financial advisor	-	1,642,867
Shares issued for payment of bridge note	1,747,500	-
Shares issued upon settlement of convertible notes	-	27,742,649

Note 1—Description of business

TuHURA Biosciences, Inc., a Nevada corporation (the "Company"), is a clinical stage immuno-oncology company with three distinct technologies focused on the development of novel therapeutics designed to overcome primary and acquired resistance to cancer immunotherapies.

Our proprietary Immune Fx™ technology platform, or IFx, is an innate immune agonist technology designed to "trick" the body's immune system to attack tumor cells by making tumor cells look like bacteria. Our lead product candidate, IFx2.0, is an innate immune agonist designed to overcome primary resistance to checkpoint inhibitors. In June 2025, we initiated a single randomized placebo-controlled Phase 3 registration trial of IFx-2.0 administered as an adjunctive therapy to Keytruda® (pembrolizumab) in first line treatment for patients with advanced or metastatic Merkel cell carcinoma who are checkpoint inhibitor naïve utilizing the FDA's accelerated approval pathway.

In addition to our IFx technology platform, in June 2025 we acquired the rights to TBS-2025, a novel VISTA-inhibiting monoclonal antibody formerly known as KVA1213, through our acquisition of Kineta Inc. ("Kineta") via merger on June 30, 2025 (the "Kineta Merger"). VISTA (otherwise referred to as *V-domain Ig suppressor of T cell activation*) is an immune checkpoint highly expressed on myeloid cells that is believed to be a strong driver of immunosuppression in the tumor microenvironment and is believed to be a primary mechanism by which leukemic blasts escape immune recognition contributing to low response rates and high rates of recurrence in acute myeloid leukemia, or AML. Following our acquisition of Kineta, we are currently planning on investigating TBS-2025 in a Phase1b/2 trial in patients with r/r *mut*NPM1AML.

In addition to IFx and TBS-2025, we are leveraging our Delta Opioid Receptor (DOR) technology to develop first-in-class bi-functional, bi-specific antibody-drug conjugates ("ADCs") targeting the DOR on Myeloid Derived Suppressor Cells ("MDSCs") to modulate their immunosuppressive influence on the bone marrow and tumor microenvironment to prevent T cell exhaustion and acquired resistance to checkpoint inhibitors and cellular therapies.

The Kineta Merger was accounted for as a business combination using the acquisition method of accounting in accordance with Accounting Standards Codification ("ASC") 805, Business Combinations. ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, Fair Value Measurements ("ASC 820") as of the acquisition date. See note 5 Merger with Kineta, Inc.

In connection with the closing of the Kineta Merger, the Company held its special meeting of the stockholders in lieu of an annual meeting on June 23, 2025 (the "Special Meeting") to submit, among other proposals, the proposal to increase the Company's authorized shares of common stock from 75,000,000 shares to 200,000,000 shares (the "Authorized Share Increase Proposal"). At the Special Meeting, the Company's stockholders approved the Authorized Share Increase Proposal, and the Company subsequently filed articles of amendment to its Articles of Incorporation to increase the number of shares of common stock authorized from 75,000,000 to 200,000,000.

Note 2—Summary of significant accounting policies

Basis for Consolidation - The consolidated financial statements of the Company have been prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP") and are presented in United States dollars. The functional currency of the Company and each of its subsidiaries is the United States dollar.

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Adgero Biopharmaceuticals Holdings Inc., Adgero Biopharmaceuticals, Inc., Kineta, LLC, and TuHURA Biosciences, Inc., a Delaware corporation ("Legacy TuHURA"). All intercompany balances and transactions have been eliminated in consolidation.

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below and have been consistently applied to all periods presented.

Reclassification – The Company reclassified the break-out of $440,340 merger-related costs for 2024 into a separate line item in the consolidated statement of operations. In the prior year, such amount had been included in the line item "general and administrative expenses".

Accounting Estimates – The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect various amounts reported in consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Deferred Offering Costs – Deferred offering costs consist of direct legal, accounting, and other fees and costs directly related to the Merger with Kintara (See note 6) and the 2025 Offerings. The Company capitalized deferred offering costs and recorded them as a direct reduction of stockholders' equity.

Property and Equipment – Property and equipment are carried at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets (generally five to seven years). Leasehold improvements are amortized straight-line over the shorter of the lease term or the estimated useful life of the asset. Property and equipment are reviewed for impairment when events or changes in circumstances indicate that the carrying amount may not be recoverable. No impairment was recorded for the years ended December 31, 2025 and 2024.

Lease Accounting – The Company recognizes right-of-use lease assets and corresponding liabilities arising from leasing activities over the requisite lease period.

Income Taxes – Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (*Topic 740*), which enhances the income tax disclosure requirements for public entities on an annual basis. Under ASU 2023-09, public entities will be required to disclose in their rate reconciliation, on an annual basis, both percentages and amounts in their reporting currency for certain categories in a tabular format, with accompanying qualitative disclosures. The amendments in ASU 2023-09 are effective fiscal years beginning after December 31, 2024, and early adoption is permitted. The Company adopted this standard and applied the disclosure requirements on a prospective basis effective for the annual reporting period ended December 31, 2025. There was no impact on the Company's consolidated financial statements and additional disclosures have been included in Note 11, Income Taxes.

Grant Income - In April 2021, the Company received approval from the Department of Health and Human Services for a $400,000 grant. The grant was to conduct research for a low-cost topical immunotherapy formulation suitable for treating cervical cancer in low and middle-income countries and low resource settings in the U.S. Additionally, the Company assumed in the reverse merger with Kintara, a $2,000,000 Business Innovation Research grant, a two year grant that was initiated in June 2023 and expired on December 31, 2025,as amended, to support the clinical development of REM-001 for the treatment of CMBC and had a remaining balance of $900,000 as of the merger date. For the years ended December 31, 2025 and 2024, the Company recognized $714,000 and $58,000 of grant income in the consolidated statements of operations.

Research and Development Expenses – Research and development consists of expenses incurred in connection with the discovery and development of product candidates. The Company expenses research and development costs as incurred.

Concentration of Credit Risk – The Company maintains cash balances in domestic financial institutions. These balances are insured by the Federal Deposit Insurance Corporation up to $250,000. As of December 31, 2025, the uninsured portion of cash held by the Company was approximately $3,634,000.

Fair Value of Financial Instruments - ASC 820, Fair Value Measurement, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's

assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or 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. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying values reported in the Company's consolidated balance sheets for cash and cash equivalents, other current assets, accounts payable, and accrued expenses are reasonable estimates of their fair values due to the short-term nature of these items.

Derivative Financial Instruments – The Company evaluates all of its agreements to determine if such instruments have derivatives or contain features that qualify as embedded derivatives. The Company accounts for certain make-whole features that are associated with convertible notes as derivative liabilities at fair value and adjusts the instruments to their fair value at the end of each reporting period. Derivative financial liabilities are initially recorded at fair value, with gains and losses arising from changes in the fair value recognized in other income (expense) in the accompanying consolidated statements of operations for each reporting period while such instruments are outstanding. The embedded derivative liabilities are valued using a probability-weighted expected return method ("PWERM"). The critical inputs used to value the PWERM are a discount rate, the estimated make-whole interest payments for various settlement scenarios and the probability of each settlement scenario. If the Company repays the noteholders or if, during the next round of financing, the noteholders convert the debt into equity, the derivative financial liabilities will be de-recognized and reclassified to the consolidated statements of stockholders' (deficit) equity on that date. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

Debt Discount and Debt Issuance Costs- Debt issuance costs are deferred and presented as a reduction to the convertible note payable. The initial fair value of the derivative liability on the make-whole premium is treated as a debt discount. Debt discount and debt issuance costs are amortized using the effective interest rate method over the term of the convertible promissory note. Amortization of debt discount and debt issuance costs are included within interest expense in the consolidated statements of operations.

Warrants – The Company has issued warrants to investors on debt and equity raises. In accordance with ASC Topic 470-20-25, when the Company issues debt with warrants, the Company treats the warrants as a debt discount, recorded as a contra-liability against the debt, and amortizes the balance over the life of the underlying debt as amortization of the discount as interest expense in the statements of operations. The offset to the contra-liability is recorded as additional paid-in capital in the Company's balance sheets if the warrants on the debt are not treated as a derivative or as liability warrants. The Company determines the fair value of the warrants at issuance using the Black-Scholes option pricing model.

Stock Compensation Expense – The Company accounts for stock-based awards to employees and nonemployees using the fair value-based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for

compensation. Fair value of each common stock option is estimated on the date of grant using the Black-Scholes valuation model. The Black-Scholes model uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of a peer group's common stock and other factors estimated over the expected term of the options. The expected term of the options granted is derived using the "simplified method" which computes expected term as the average of the sum of the average vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

Common Stock Valuation – We are required to estimate the fair value of the common stock underlying our equity awards when performing fair value calculations. Prior to our shares trading on the Nasdaq Capital Markets on October 18, 2024, the fair value of the common stock underlying our equity awards was determined on each grant taking into account input from management and the pricing offered in our equity raises. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant. In the absence of a public trading market for our common stock, on each grant date we develop an estimate of the fair value of our common stock in order to determine an exercise price for the option grants. Our determinations of the fair value of our common stock were made by considering the prices of preferred stock sold to investors in arm's length transactions and the rights, preferences and privileges of our preferred stock relative to those of our common stock.

Business Combinations and Asset Acquisitions – We account for acquired businesses using the acquisition method of accounting, which requires that the assets acquired, and liabilities assumed be recorded at the date of acquisition at their respective fair values if the acquisition meets the definition of a business combination. If the acquisition does not meet the definition of a business combination, then it is accounted for as an asset acquisition and the purchase consideration is allocated to the acquired assets.

ASC 805, Business Combinations, provides a model for determining whether an acquisition represents a business combination. In order to be a business, the integrated set of activities of the acquired entity needs to have an input and a substantive process that together significantly contribute to the ability to create outputs. The acquired entity must also pass the "Screen Test" which involves determining whether the acquisition represents an in-substance asset acquisition based on whether the fair value of the gross assets acquired is "substantially all" concentrated in a single asset or group of similar assets. This evaluation excludes certain acquired assets such as cash, deferred taxes, and goodwill associated with deferred taxes, but includes all other gross assets, including any consideration transferred in excess of the identified assets.

Indefinite-Lived Intangible Assets – Indefinite-lived intangible assets consist of In-Process Research and Development ("IPR&D"). The fair values of IPR&D project assets acquired in business combinations are capitalized. We utilized the Cost Method to determine the estimated fair value of the IPR&D assets acquired in our recent business combination with Kineta. These assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are amortized over the remaining useful life or written off, as appropriate.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. The Company considers many factors in evaluating whether the value of our intangible assets with indefinite lives may not be recoverable, including, but not limited to, the cost of equity and debt capital, general economic conditions, outlook and market performance of the Company's industry and recent and forecasted financial performance.

We will evaluate indefinite-lived intangible assets for impairment at least annually and whenever facts and circumstances indicate that their carrying amounts may not be recoverable.

Goodwill – Goodwill represents the amount of consideration paid in excess of the fair value of net assets acquired as a result of the Company's business acquisitions accounted for using the acquisition method of accounting. Goodwill is not amortized and is subject to impairment testing at a reporting unit level on an annual basis or when a triggering event occurs that may indicate the carrying value of the goodwill is impaired. An entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is

more likely than not that the fair value of the reporting units is less than its carrying amount.

We will evaluate goodwill for impairment at least annually and whenever facts and circumstances indicate that their carrying amounts may not be recoverable.

Segment data - The Company operates in one reportable segment, which includes all activities related to advancing therapies for cancer treatment. The determination of a single reportable segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker (CODM), which is its chief executive officer, who reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources and planning and forecasting for future periods. The measure of segment assets is reported on the balance sheet as total assets. There is no segment revenue for the years ended December 31, 2025, and 2024. The accounting policies of the cancer treatment segment are the same as those described in the summary of significant accounting policies. All tangible assets are held in the United States.

Net loss per share - Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the Company has reported net losses for each period presented.

Note 3—Liquidity and management's plans

The Company has been engaged in research and development activities related to ImmuneFx, the Company's patented product, which will require additional investment until revenue-generating activities can begin.

The Company has historically incurred negative cash flows from operations.

For the year ended December 31, 2025, the Company incurred $27.6 million of negative cash flows from operations. The Company has approximately $3.6 million of cash and cash equivalents on hand at December 31, 2025. The Company expects that its existing capital resources, including the $7.0 million Registered Direct Offering funds received in the first quarter of 2026 will be sufficient to fund the Company's planned future operations into the early third quarter of 2026.

The Company expects to raise cash through the sale of capital stock and warrants, debt issuances, obtaining grants, or commercial partnerships. However, there can be no assurance that any fundraising will be achieved or on commercially reasonable terms, if at all. As such, there is substantial doubt about the Company's ability to continue as a going concern for the next 12 months from date that the financial statements were available to be issued.

Note 4—Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Years Ended December 31,	
	2025	**2024**
Numerator:		
Net loss attributable to common stockholders	$ (30,060,333)	$ (22,649,572)
Denominator:		
Weighted-average common shares outstanding - basic and diluted	47,927,196	18,662,690
Net loss per share attributable to common shareholders - basic and diluted	$ (0.63)	$ (1.21)

Common stock warrants in the amount of 297,029 issued to our financial advisor, H.C. Wainwright & Co., LLC, were not outstanding as common shares as of December 31, 2025 and 2024, however included in the weighted-average common shares outstanding – basic and diluted as if they were considered outstanding.

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. For the years ended December 31, 2025 and 2024, the Company excluded the following potential common shares from the computation of diluted net loss per share attributable to common stockholders for the period because including them would have had an anti-dilutive effect:

	As of December 31,	
	2025	**2024**
Stock options issued and outstanding	18,031,425	6,403,818
Unvested restricted stock units	57	114
Warrants	23,644,268	10,609,855
Total	41,675,750	17,013,787

Note 5—Merger with Kineta, Inc.

On June 30, 2025, the Company acquired 100% of the issued and outstanding capital stock of Kineta pursuant to the terms of the TuHURA-Kineta Merger Agreement. Kineta is a clinical-biotechnology company, with a mission to develop next-generation immunotherapies, focused on discovering and developing potentially differentiated immunotherapies that address the mechanism of cancer immune resistance. Kineta's VISTA blocking immunotherapy, KVA12123, was acquired along with worldwide patents, patent rights, patent applications, product and development program assets, technical and business information, and other rights and assets derived from the development program. The Company renamed the VISTA blocking immunotherapy technology from KVA12123 to TBS-2025. The Company anticipates synergies, such as having control over the VISTA blocking immunotherapy development program, continuing employment of Kineta former CEO, and a consulting agreement with Kineta's former CSO, will further enhance our activities advancing therapies for cancer treatment.

Goodwill will not be deductible for tax purposes.

The allocation of the consideration for the net assets acquired for the acquisition of Kineta were as follows.

		June 30, 2025
Purchase Consideration		
Exclusivity cash deposit	$	5,994,502
Equity issued to Kineta shareholders		6,396,017
Holdback liability issued in equity		2,519,644
Cash previously advanced for clinical trial funding and working capital		1,650,000
Fair value of consideration	$	16,560,163
Assets Acquired:		
Cash	$	390,721
Acquired in-process research and development		11,275,000
Total assets acquired		11,665,721
Liabilities Assumed:		
Accrued expenses, assumed debt, and severance liabilities	$	(5,645,721)
Deferred tax liability		(197,919)
Total liabilities assumed		(5,843,640)
Net assets acquired		5,822,081
Goodwill	$	10,738,082

The fair value of equity was determined based on the closing price of the Company's common stock immediately prior to the Kineta Merger, and included 3,998,053 shares of common stock at $2.23 per share. There were 1,129,885 shares of delayed consideration to satisfy any necessary adjustments, including any net working capital adjustments, and recorded at its acquisition date fair value and classified as a liability within current liabilities as holdback liability on the Company's consolidated balance sheets at the acquisition date.

Ultimately, as of December 31, 2025, there were 3,997,761 shares of the Company's common stock (adjusted for fractional shares) issued under the TuHURA-Kineta Merger Agreement.

The delayed consideration was settled in Company shares of common stock and recorded at its fair value through the settlement date of December 30, 2025 with changes recorded to earnings. Additionally, the estimated fair value of the delayed consideration settled in equity used both observable and unobservable inputs, specifically considering the price of the Company's common stock, as well as the probability of the payout at the end of the holding period, and considered a Level 3 measurement as defined in ASC 820. Changes in fair value are recognized in the consolidated statements of operations under change in fair value of Kineta merger holdback shares. On December 30, 2025, the Company issued 1,129,593 using a closing price of $0.76 and recognized a gain of $1,590,949 for the year ended December 31, 2025 due to the change in fair value.

Included in consideration transferred is the settlement of the pre-existing Clinical Trial Funding Agreement and working capital loans owed by Kineta to the Company, which were effectively settled and became intercompany arrangements as of the closing of the transaction. The settlement of pre-existing relationships between the Company and Kineta did not result in any material gain or loss.

The Company estimated the fair value of the IPR&D assets using the cost approach, which is based on the amount that a market participant would incur to recreate the assets, adjusted for obsolescence, inefficiencies, and the current stage of completion of the underlying development efforts. Significant assumptions used in the valuation included estimates of direct and indirect development costs and te Company's weighted average cost of capital.

The fair value of the assumed accounts payable, accrued expenses and notes payable were deemed to be equivalent to their carrying value due to the short-term nature of their obligations.

The Company incurred approximately $3.7 and $0.4 million in transaction costs for the Kineta Merger during the years ended December 31, 2025 and 2024, respectively, and recorded as acquisition-related costs in the Company's consolidated statements of operations.

The following unaudited pro forma financial information reflects the consolidated results of operations of TuHURA as if the acquisition of Kineta had taken place on January 1, 2024 and January 1, 2025. The pro forma information includes acquisition-related expenses. The pro forma financial information is not necessarily indicative of the results of operations as they would have been had the transaction been effected on the assumed date.

	Year ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development expenses	22,153,738	18,722,316
General and administration expenses	15,348,333	12,459,176
Operating Loss	(37,502,071)	(31,181,492)
Other (Expense) Income:		
Gain on sale of assets	1,011,799	-
Employee retention tax credit	113,574	-
Grant income	713,508	57,627
Gain (loss) on liabilities settlement	111,072	-
Changes in fair value measurements	1,590,949	(4,154,772)
Interest income (expense), net	(508,795)	(3,540,669)
Total Other (Expense) Income	3,032,107	(7,637,814)
Net Loss	$ (34,469,964)	$ (38,819,306)

Note 6 – Merger with Kintara Therapeutics

On October, 18, 2024, the Company's Merger with Kintara Therapeutics closed. Under the terms of the Merger, immediately prior to the effective time of the Merger, shares of the Company’s preferred stock were converted into shares of Company common stock and all of the Notes issued by the Company were converted into shares of Company common stock pursuant to the terms therein. At the effective time of the Merger, (i) Kintara issued an aggregate of approximately 40,441,605 shares of its common stock to Company stockholders, based on an exchange ratio of 0.1789 (after giving effect to the Reverse Stock Split) shares of Kintara’s common stock for each share of Company common stock outstanding immediately prior to the Merger, (ii) each then-outstanding Company stock option was assumed and converted into an option to purchase shares of Kintara common stock subject to certain adjustments based on the exchange ratio as set forth in the Merger Agreement, and (iii) each then-outstanding warrant to purchase shares of Company Common Stock was assumed and converted into and exchangeable based on the exchange ratio for a warrant of like tenor entitling the holder to purchase shares of Kintara common stock.

The Kintara merger was accounted for as a reverse recapitalization under which the historical financial statements of the Company prior to the Merger are the historical financial statements of the accounting acquirer, Legacy TuHURA. All share, per share and related information presented in the consolidated financial statements and notes prior to the Merger has been retroactively adjusted to reflect the Exchange Ratio and Reverse Stock Split for all periods presented. Immediately after the merger, there were 42,032,165 shares of the Company’s common stock outstanding.

The following table shows the net liabilities assumed in the merger:

	October 18, 2024
Cash and cash equivalents	$ 70,097
Prepaid and other assets	370,030
Accounts payable and accrued expenses	(1,787,039)
Total net liabilities assumed	(1,346,912)
Plus: merger transaction costs	(4,129,663)
Total net liabilities assumed plus merger transaction costs	$ (5,476,575)

In connection with the Merger, Kintara entered into a Contingent Value Rights Agreement (the "CVR Agreement") with Equiniti Trust Company, LLC, pursuant to which the holders of Kintara common stock and Kintara common stock warrants, as of immediately prior to the consummation of the Merger, received one contingent value right (a "CVR") for each outstanding share of common stock held by such stockholder (or, in the case of warrants, each share of common stock for which such warrant is exercisable into). Following the achievement of certain prescribed milestones, each CVR holder received in December 2025 its pro rata portion of 1,539,918 shares of TuHURA common stock.

Note 7—Other current assets

Other current assets consist of the following as of December 31, 2025, and 2024:

	December 31, 2025	December 31, 2024
Employee Retention Tax Credit	$ -	$ 214,699
NIH Grant Receivable	-	222,702
Clinical trial deposit	167,661	204,955
Other current assets	333,526	316,352
	$ 501,187	$ 958,708

Note 8—Property and equipment, net

Property and equipment, net consists of the following as of December 31, 2025, and 2024:

	December 31, 2025	December 31, 2024
Furniture and fixtures	$ 170,607	$ 170,607
Leasehold improvements	544,629	544,629
Machinery and office equipment	1,671,721	1,423,183
Software	72,394	72,394
	2,459,351	2,210,813
Less accumulated depreciation and amortization	(2,158,712)	(2,087,447)
	$ 300,639	$ 123,366

Depreciation and amortization of property and equipment totaled approximately $71,000 and $117,000 for the years ended December 31, 2025, and 2024, respectively.

Note 9—Accounts payable and accrued expenses

Accounts payable and accrued expenses consist of the following as of December 31, 2025, and 2024:

	December 31, 2025	December 31, 2024
Trade accounts payable	$ 3,770,124	$ 3,152,816
Accrued compensation	1,525,139	1,161,650
Other accrued expenses	227,624	855,700
	$ 5,522,887	$ 5,170,166

Note 10—Debt

Assumed debt from Kineta Merger

As part of the Kineta Merger, the Company assumed debt with a fair value in the amount of $434,000. The assumed debt was settled and paid in July 2025.

Promissory notes to former Kineta employees

In exchange for separation payments assumed from the Kineta Merger for five of the former Kineta employees, the Company issued promissory notes totaling approximately $590,000 in the aggregate at 10% interest payable monthly from September 2025 to February 2026. The current balance is approximately $197,000 and interest payments of $39,000 were paid as of December 31, 2025

Bridge Loan Transaction

On October 27, 2025, the Company entered into a Secured Promissory Note and Loan Agreement (the "Loan Agreement") with an accredited investor and shareholder of the Company (the "Lender"). Pursuant to the terms of the Loan Agreement, the Lender agreed to make loans to the Company in an aggregate principal amount of up the $3,000,000 (the "Loans") during a 30-day availability period beginning on the date of the Loan Agreement. The monthly interest rate on the Loan Agreement was 3.0% and had a maturity date of December 31, 2025. On December 2, 2025, the Company and the Lender entered into an amendment to the Loan Agreement (the "Amendment") pursuant to which (i) the Lender agreed to extend the 30-day availability period to December 5, 2025, and (ii) the Company and Lender agreed that warrants issuable to the Lender under the Loan agreement would consist of a warrant to purchase 150,000 shares of Company common stock for each $1.5 million of funds borrowed under the Loan Agreement (including the First Loan), prorated for borrowings less than $1.5 million. Except for the forgoing, the Amendment included no further changes to the original loan agreement.

The Lender advanced $1,500,000 on October 27, 2025 and $1,500,000 on December 2, 2025 that were used for working capital purposes. On December 12, 2025, the Company paid $1,500,000 principal balance, $180,000 in loan fees and $15,000 in interest payments. The remaining $1,500,000 principal balance, $180,000 in loan fees, and $67,500 in interest was exchanged for 1,059,090 shares of common stock in the registered direct offering (see note 12).

In addition, on the date of the First loan and Second loan, the Company issued warrants in an aggregate of 65,217 and 234,783 with an exercise price of $2.30 and $1.81 to purchase shares of Company common stock (the "Lender Warrant"). The Lender Warrant is immediately exercisable and will expire on the date that is two years from the date of issuance. The Company determined that the relative fair value of the Bridge Loan Warrants amounted to $301,424 and recognized as a debt discount with an offset to additional paid in capital. The fair value associated with the warrants was determined using Black-Sholes pricing model using the terms of the agreement and the following assumptions - expected term of 2 years, dividend yield of 0.0%, volatility of 110.5% and a risk free rate of 3.48%.

Convertible promissory notes

On various dates beginning on December 11, 2023 through September 18, 2024, the Company completed a private placement

in which the Company issued Convertible Promissory Notes (the "Notes") with various entities at various amounts for an aggregate of $31,253,000. The Notes bear interest at a rate of twenty percent (20%) per annum and were scheduled to mature on the second anniversary of the issuance date. In addition, the investors in the private placement also received common stock purchase warrants (the "2024 Warrants") in the event they subscribe to purchase Notes in the aggregate principal amount of more than $4.0 million or more, with such number of 2024 Warrants being equal to 50% of the aggregate principal amount of the Note purchased divided by $3.80. The 2024 Warrants related to these Notes have an exercise price of $5.70 per share and expire three years from the date of issuance. On October 18, 2024, under automatic conversion features upon the occurrence of a reverse public merger transaction, the convertible notes payable converted to common stock and the derivative liability associated with the make-whole provision discussed below was reclassified to additional paid-in capital.

Conversion feature under reverse public merger transaction

Under a reverse public merger transaction, the Notes convert at the sum of (a) the outstanding principal balance and unpaid accrued interest at the time of the transaction, plus (b) a Make-Whole Amount premium, defined in the Notes as additional interest to be incurred until the next period end date as defined in the Notes, divided by a conversion price equal to $3.80. Upon closing of the Kintara merger on October 18, 2024, the Notes were converted into shares of common stock.

The Company evaluated the terms of the Notes for embedded conversion features in accordance with ASC 815-15-25 and determined that the conversion features meet the definition of an embedded derivative liability that is required to be bifurcated from the host instrument and measured at fair value, with subsequent changes in fair value recognized in the consolidated statement of operations. Management used a scenario-based analysis to estimate the fair value of the bifurcated embedded derivative liability at issuance of the Notes. The Company recognized debt discount of $2,539,227 upon issuance of the Notes.

Warrants issued in connection with convertible notes

The 2024 Warrants were identified as freestanding financial instruments and determined to be indexed to the Company's own stock. Further, the 2024 Warrants were not precluded from being classified within equity. As such, the proceeds received upon issuing the Notes were first allocated to the fair value of the bifurcated embedded derivative with the remainder allocated to the debt host instrument and 2024 Warrants (within additional paid in capital) on a relative fair value basis. Subsequent fair value measurement is not required as long as the instrument continues to be classified in equity. The Company determined that the fair value of the 2024 Warrants in connection with Notes issued amounted to $6,520,056 and recognized as a debt discount with an offset to additional paid in capital.

The following table presents a roll-forward of Debt for the years ended December 31, 2025 and 2024. respectively:

Balance as of January 1, 2024	$ 2,698,564
Issuance of convertible notes payable	28,568,000
Interest expense	2,859,878
Converted to common stock	(34,126,442)
Balance as of December 31, 2024	$ -
Assumed Kineta Debt	434,000
Notes payable to former Kineta employees	592,063
Bridge loan transaction	3,000,000
Interest expense and loan fees	301,971
Bridge loan transaction payment in common stock	(1,747,500)
Payments of Assumed Kineta Debt, Notes Payable to former Kineta employees, and Bridge Loan transaction	(2,383,180)
Balance as of December 31, 2025	$ 197,354

The following table presents a roll-forward of the Debt discount for the years ended December 31, 2025 and 2024. respectively:

Balance as of January 1, 2024	$ (374,406)
Debt issue costs	(1,218,525)
Debt discount associated with make-whole features recognized	(2,402,228)
Debt discount associated with warrants recognized	(6,520,058)
Amortized to interest expense	1,278,424
Reclassified to additional paid-in capital upon conversion of convertible notes payable	9,236,793
Balance as of December 31, 2024	$ -
Debt Discount associated with Bridge loan transaction loan fees	(180,000)
Debt discount associated with Bridge loan transaction warrants recognized	(301,424)
Amortized to interest expense	481,424
Balance as of December 31, 2025	$ -

Note 11—Income taxes

The components of income before provision for income taxes are as follows:

	2025	2024
Domestic	$ (30,051,977)	$ (21,682,306)
Net loss before income taxes	$ (30,051,977)	$ (21,682,306)

The components of the provision for income taxes are as follows:

	2025	2024
Current provision		
Federal	$ -	$ -
State	1,600	3,768
Total current provision	$ 1,600	$ 3,768
Deferred provision		
Federal	-	-
State	-	-
Total current provision	$ -	$ -
Total provision for income taxes	$ 1,600	$ 3,768

The Company is subject to taxation in the United States both the federal level and within Florida and California. The Company is not currently under audit, and the statute of limitations for tax assessments, is three years at the federal law, four years in California, and five years in Florida.

Beginning in 2025 annual reporting , the Company adopted ASU 2023-09 prospectively. See Note 1 - Summary of Significant Accounting Policies - Recently Adopted Accounting Pronouncements for additional details on the adoption of ASU 2023-09. A reconciliation of the U.S. federal statutory income tax rate to our effective tax rate pursuant to the disclosure requirements of ASU 2023-09 for the year ended December 31, 2025 is as follows:

	Year Ended December 31, 2025	
U.S. federal statutory income tax rate	$ (6,320,827)	21.00%
State and local income taxes, net of federal income tax effect (1)	1,600	-0.01%
Tax credits		
Research and development tax credits	(380,513)	1.26%
Nontaxable or nondeductible items		
Transaction costs	613,777	-2.04%
Other	28,441	-0.09%
Change in valuation allowance	(74,020,868)	245.93%
Other adjustments		
Deferred only - Stock compensation	751,167	-2.50%
Deferred only - Accrued Expenses	325,657	-1.08%
Deferred only - NOL Write off	60,615,597	-201.39%
Deferred only - R&D Credit Write off	18,354,397	-60.98%
Other	33,172	-0.11%
Effective tax rate	$ 1,600	-0.01%

(1) California and Florida account for 100% of the tax effect in this category

The reconciliation of the statutory U.S. federal income tax rate to the Company's effective tax rate for the year ended December 31, 2024 were as follows

	2024
U.S. statutory rate	21.00%
State taxes, net of federal	4.33%
Change in valuation allowance	1.65%
Return to provision - 2023 Tax Free Reorganization	-18.89%
Return to provision - Other	-0.46%
R&D Credit	-1.65%
Other permanent differences	-6.00%
Effective tax rate	-0.02%

Cash paid for income taxes, net of refunds received, by jurisdiction pursuant to the disclosure requirements of ASU 2023-09 for the year ended December 31, 2025 is as follows:

	2025
Federal	$ -
State	
California	-
Florida	-
Cash paid for income taxes, net of refunds received	$ -

The table below presents the effects of temporary differences that give rise to significant portions of deferred tax assets and liabilities as of December 31, 2025 and 2024:

	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 94,384,902	$ 25,098,126
Stock compensation expense	2,718,674	2,467,541
Accrued payroll	373,904	294,420
Section 174 R&D	7,641,344	6,172,416
Intangible assets	68,217	26,272
Lease liability	123,234	51,334
Depreciation	27,357	94,926
Capital loss carryforward	10,996,460	10,889,722
R&D credits	6,698,028	1,451,300
Other	72	—
Total gross deferred tax assets	$ 123,032,192	$ 46,546,057
Less valuation allowance	(120,371,653)	(46,494,883)
Net deferred tax assets	$ 2,660,539	$ 51,174
Deferred tax liabilities		
IPR&D	$ (2,764,186)	$ -
Accrued expense	-	(697)
ROU asset	(94,272)	(50,477)
Total deferred tax liabilities	$ (2,858,458)	$ (51,174)
Total deferred tax assets / (liabilities)	$ (197,919)	$ -

The Company has Federal and State net operating loss (“NOLs”) carryforwards of approximately $416.4 million and $154.9 million, respectively, as of December 31, 2025 and 2024. $334.2 million in federal NOLs were generated in tax years beginning prior to January 1, 2018 and can be deducted at 100% of income, some of these NOLs start to expire in 2026. The remaining Federal NOLs of $82.2 million were generated in tax years beginning on or after January 1, 2018 and have an infinite carryforward period but are subject to 80% deduction limitation based upon pre-NOL deduction taxable income. State NOLs generated have various expiration rules and dates with the first amount of NOLs expiring in 2027.

The utilization of the Company’s net operating loss carryforwards and research tax credit carryovers could be subject to annual limitations under Section 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), and similar state tax provisions, due to ownership change limitations that may have occurred previously or that could occur in the future. These ownership changes limit the amount of net operating loss carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383 of the Code, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period.

The Company has approximately $0.2 million of federal and state deferred tax liabilities which the Company expects will be a future source of income for which deferred tax benefit can be recognized in the U.S. After consideration of this income source, the Company has net deferred tax assets of $123.0 million before considering the valuation allowance.

The Company has completed a scheduling exercise to demonstrate the timing of the reversal of its taxable temporary differences to ensure they will reverse in a period in which the deferred tax assets are available to be utilized. Based on this analysis, the Company concluded that federal and deferred tax assets would be available to be utilized in all such periods with the exception of certain tax years where an IPR&D related taxable difference is expected to generate future taxable income. Accordingly, a deferred tax liability has been recorded for the expected amount of deferred tax liabilities that cannot be offset by deferred tax assets.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2025 and 2024.

The Company performed a comprehensive review of its portfolio of uncertain tax positions in accordance with recognition standards established by GAAP. In this regard, an uncertain tax position represents the Company's expected treatment of a tax position taken in a filed tax return or planned to be taken in a future tax return that has not been reflected in measuring income tax expense for financial reporting purposes. The Company has determined that it does not have any material uncertain tax positions. The Company has not recorded any interest or penalties related to any uncertain tax positions in the consolidated statement of operations.

On July 4, 2025, the One Big Beautiful Act ("OBBBA") was enacted in the U.S. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provision of the Tax Cuts and Jobs Act, modification to the international tax framework and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in 2025 and other implemented through 2027. The Company does not anticipate the bill will have a material impact on the financial statements.

Note 12—Stockholders' equity

Immediately prior to the closing of the Kintara Merger, all outstanding shares of Company preferred stock were converted into shares of Company common stock (which were converted into shares of Kintara common stock in the Merger), and upon completion of the merger, all warrants of the Company were converted into warrants to purchase Kintara common stock. All outstanding shares of the Company's Preferred Stock were converted into 16,912,843 shares of common stock.

As of December 31, 2025, the Company had two classes of stock defined in its Amended and Restated Articles of Incorporation (the "Articles).

Common Stock – The Company is authorized to issue up to 200,000,000 shares of Common Stock based on the Articles. Holders of common stock are entitled to one vote for each share of common stock. As of December 31, 2025, there were 59,336,104 shares of common stock outstanding.

Preferred Stock – The Company is authorized to issue up to 5,000,000 shares of Preferred Stock based on the Articles.

The historical Kintara Series A Preferred Stock were assumed from the Kintara Merger has a stated value of $278,530 as of December 31, 2025.

ATM Offering

On November 3, 2025, the Company and H.C. Wainwright & Co., LLC ("Wainwright") entered into an At-The-Market Offering Agreement (the "Offering Agreement") with respect to an at-the-market offering program under which the Company may sell shares of its common stock having an aggregate offering price of up to $50,000,000 through Wainwright as its sales agent. The Company has not issued any shares under the Offering Agreement as of December 31, 2025.

Private Placement

From June 2, 2025 to December 31, 2025, the Company entered and completed a private placement transaction in which it issued and sold 4,759,310 shares of common stock and warrants to purchase an aggregate of 4,759,309 shares of common stock. The Company received net proceeds of $11.2 million. Additionally, the Company issued warrants to purchase an aggregate of 189,616 shares of common stock to Paulson, the placement agent for this transaction There was $0.5 million from this offering that was

purchased on December 31, 2025 (funded in January 2026) and included in the Company's consolidated balance sheets under Stock subscription receivable.

Registered Direct Offering

On December 9, 2025, the Company entered and completed the first closing of a registered direct offering in which it issued and sold 5,219,999 shares of common stock, Series A and Series B warrants to purchase an aggregate of 5,219,999 and 5,219,999 shares of common stock, respectively. The Company received net proceeds of $7.2 million. Additionally, the Company issued warrants to purchase an aggregate of 283,873 shares of common stock to Wainwright, the placement agent for this transaction at an exercise price of $2.0625 per share.

Shares issued to Former Kineta Employees

Subsequent to the completion of the Kineta Merger, the Company entered into consulting agreements with five former Kineta employees which provides for the payment of stock awards under the TuHURA Biosciences, Inc. 2024 Equity Incentive Plan (the "2024 Equity Plan"). The amounts payable of approximately $592,000 to such former Kineta employees are in satisfaction of separation payments that were assumed in connection with the Kineta Merger. Approximately 133,000 shares of common stock were issued at $2.50 per share under the 2024 Equity Plan. The Company recorded a loss in the amount of approximately $185,000 under other expense in the consolidated statements of operations.

Warrants – The following table summarizes the Company's outstanding common stock warrants as of December 31, 2025

	Outstanding	Weighted average exercise price	Expiration dates
Historical TuHURA common stock warrants	7,661,273	$ 4.58	January 2026 to December 2030
Historical Kintara common stock warrants	10,199	$ 757.65	October 2026 to April 2027
2024 common stock warrants issued to financial advisor	297,029	$ 0.01	April 2027
PIPE investors common stock warrants	4,759,309	$ 3.31	December 2030
PIPE placement agent common stock warrants	189,616	$ 3.31	December 2030
Bridge loan common stock warrants	300,000	$ 1.92	October 2027 to December 2027
RDO Series A investors common stock warrants	5,219,999	$ 1.95	June 2031
RDO Series B investors common stock warrants	5,219,999	$ 1.95	December 2027
RDO placement agent common stock warrants	283,873	$ 2.06	December 2030

Warrant modifications

In August 2024, the Company extended the exercise period of its common stock purchase warrants issued in connection with Legacy TuHURA Series A Preferred Stock (the "Legacy Series A Warrants") for an additional six months, with a new expiry date of February 12, 2025. There were no other changes in the terms of the Legacy Series A Warrants. As a result, a deemed dividend to the holders of the Legacy Series A Warrants in the amount of $965,177 was recorded as an increase in the net loss attributable to the common stockholders for the year ended December 31, 2024. The incremental value associated with the warrant modification was determined using a Black-Sholes pricing model using the original terms of the warrants and the modified terms of the warrants and the following assumptions: expected term of approximately 0.1 - 0.6 years, dividend yield of 0.0%, volatility of 75% -112%, and a risk free rate of 5.4% to 5.5%.

On September 5, 2025, certain Purchases (the "Deferral Investor") who agreed to invest an aggregate of $4.0 million or more in the Offering from June 2, 2025 and elected to defer $3.7 million to be purchased or funded by December 31, 2025, entered into an agreement (the "Final Purchase Agreements") pursuant to which they agreed to immediately purchase an aggregate of $3.2 million of the Final Tranche Offering Amount in exchange for the Company's agreement, set forth in a Warrant Amendment Agreement between the Company and each Deferral Investor (the "Warrant Amendment Agreements"), to extend the expiration dates of certain warrants to purchase an aggregate of 1.5 million shares of Company common stock that were issued by the Company's predecessor in a 2024 private placement of convertible notes (the "2024 Warrants"). Under the Warrant Amendment Agreements, the expiration

dates of the 2024 Warrants was extended to December 31, 2030. The modification of the 2024 Warrants was related to the Offering and the incremental fair value relating to the modification has no net equity effect.

"Penny" warrants

There were 297,029 warrants issued to our financial advisor, Wainwright, related to merger transaction costs in connection with the Merger. The warrants are considered “penny” warrants and are considered common stock outstanding as of December 31, 2025 (see note 4). The accounting for the warrants is determined to have zero net effect on total equity as of December 31, 2025. The fair value associated with the warrants was determined using Black-Sholes pricing model using the terms of the agreement and the following assumptions expected term of approximately 2.4 years, dividend yield of 0.0%, volatility of 120.4% and a risk free rate of 4.15% resulting in an estimated valuation of approximately $1,600,000.

Warrants exercised

There were 1,208,104 warrants and 646,580 warrants that were exercised in the years ended December 31, 2025 and 2024, respectively. and proceeds in the amount of $3,620,657 and $1,944,765. All outstanding warrants entitled the holder thereof to purchase one share of Company common stock.

Note 13—Stock option plans

Stock options

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock-based awards on the date of grant. The assumptions employed in the calculation of the fair value of share-based compensation expense were calculated as follows for all periods presented:

	2025	2024
Weighted average common stock value	$ 1.49	$ 4.76
Risk free interest rate	3.82% - 4.66%	4.10% - 4.35%
Expected dividend yield	0%	0%
Expected term	6.0 years	6.0 years
Expected stock volatility	101.9% - 105.3%	100.1% - 103.0%

Below is a summary of stock option activity for the year ending December 31, 2025:

	Number of options	Weighted Average Exercise Price	Weighted Average Contractual Life
Outstanding at December 31, 2024	6,403,818	$ 5.11	7.44 years
Forfeited and cancelled	(394,487)	$ 3.79	
Exercised	(307,633)	$ 2.11	
Granted	12,329,727	$ 1.49	
Outstanding at December 31, 2025	18,031,425	$ 2.35	8.91 years
Exercisable at December 31, 2025	3,257,047	$ 4.94	5.39 years

Options outstanding had an intrinsic value of $0 and $5,494,000 as of December 31, 2025 and December 31, 2024, respectively. As of December 31, 2025, there was $21,500,000 of unrecognized stock compensation, which will be recognized over the next three years.

Restricted Stock units

Restricted stock units (“RSU”) were assumed from the Merger issued to the former Kintara Chief Executive Officer and

currently is a director of the Company, and 57 shares vested on August 1, 2025. The remaining shares assumed from the Merger, will vest on August 1, 2026, and such shares are not accounted for until they vest.

Stock compensation expense

Total stock-based compensation expense was allocated as follows:

	2025	2024
General and administrative	$ 2,051,112	$ 843,111
Research and development	4,373,618	1,115,552
Total stock-based compensation expense	$ 6,424,730	$ 1,958,663

Note 14—Commitments and contingencies

Lease Commitments – The Company leases facilities under non-cancelable operating leases for the laboratory and offices in Tampa, Florida. The current lease was extended in December 2025 and expires in March 2028. Additionally the Company entered into a finance lease for laboratory equipment in June 2025. Operating leases are included in operating lease right of use assets, lease liability, current and long term. Finance leases are included in property and equipment, lease liability, current and long term.

Future minimum lease payments under these leases are as follows:

	Finance	Operating
Year ending December 31, 2026	$ 51,971	$ 186,034
Year ending December 31, 2027	51,971	196,221
Year ending December 31, 2028	25,985	49,650
Interest portion of right of use liability	(11,789)	(47,375)
Finance and operating lease liabilities	$ 118,138	$ 384,530

Operating leases - Total lease expense was approximately $172,000 and $163,000 for the years ended December 31, 2025 and 2024, respectively.

Cash paid for amounts included in the measurement of lease liabilities was approximately $173,000 and $160,000 for the years ended December 31, 2025 and 2024.

For the current lease, the weighted-average lease term is 2.25 years and 1.25 years and the weighted average discount rate is 10.0% as of December 31, 2025 and 2024.

Finance leases- Cash paid for amounts included in the measurement of finance lease liabilities was $54,315 for the year ended December 31, 2025. There were no finance leases for the year ended December 31, 2024. Interest on the finance lease liabilities amounted to approximately $5,000 for the year ended December 31, 2025.

For the current finance lease, the weighted-average lease term is 2.5 years and the weighted average discount rate is 7.5% as of December 31, 2025.

Employment Agreements – The Company maintains employment agreements with its Chief Executive Officer and Chief Financial Officer, each entered into in May 2023 by Legacy TuHURA, as amended and as subsequently assumed by the Company in connection with the closing of the Merger.

Future minimum payments under these employment agreements are as follows:

Year ending December 31, 2026	$	874,000
	$	874,000

Note 15—Subsequent events

Subsequent events – The Company has evaluated subsequent events through March 31, 2026 in connection with the preparation of these financial statements, which is the date the financial statements were available to be issued.

Registered Direct Offering

In the first quarter of 2026, the Company completed the second and third closing from the December 2025 registered direct offering in which it issued and sold 4,242,424 shares of common stock, Series A and Series B warrants to purchase an aggregate of 4,242,424 and 4,242,424 shares of common stock. The Company received gross proceeds of $7.0 million.