



# 2022 Annual Report



**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, 2022**

**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 001-38914**

**Celularity Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**170 Park Ave**

**Florham Park, NJ**

(Address of principal executive offices)

**83-1702591**

(I.R.S. Employer  
Identification No.)

**07932**

(Zip Code)

**Registrant's telephone number, including area code: (908) 768-2170**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value \$0.0001 per share	CELU	The Nasdaq Stock Market LLC
Warrants, each exercisable for one share of Class A common stock at an exercise price of \$11.50 per share	CELUW	The Nasdaq Stock 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 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, 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 voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of Class A common stock on the Nasdaq Stock Market on June 30, 2022, was \$227.4 million.

The number of shares of the registrant's Class A common stock outstanding as of March 27, 2023 was 165,028,879.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement, or the Proxy Statement, for the Registrant's 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year ended December 31, 2022.





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On July 16, 2021, we consummated the previously announced merger pursuant to that certain Merger Agreement and Plan of Reorganization, dated January 8, 2021, or the Merger Agreement, by and among us, our wholly-owned merger subs and Celularity LLC (formerly known as Celularity Inc.), or Legacy Celularity.

Pursuant to the terms of the Merger Agreement, we effected the business combination through the (a) merger of our wholly-owned merger sub with and into Legacy Celularity with Legacy Celularity surviving as our wholly-owned subsidiary and (b) immediately following the first merger and as part of the same overall transaction, the merger of the Legacy Celularity, as surviving corporation of the first merger, with and into a second wholly-owned merger sub, with such second wholly-owned merger sub as the surviving entity of the second merger, which ultimately resulted in Legacy Celularity becoming our wholly-owned direct subsidiary. We refer to these mergers as the “Mergers” and, collectively with the other transactions described in the Merger Agreement, the “Business Combination”. On the Closing Date, we changed our name from GX Acquisition Corp. to Celularity Inc.

Unless the context indicates otherwise, references in this annual report to the “Company,” “Celularity,” “we,” “us,” “our” and similar terms refer to Celularity Inc. (f/k/a GX Acquisition Corp.) and its consolidated subsidiaries (including Legacy Celularity). References to “GX” refer to the predecessor company prior to the consummation of the Business Combination.

The Celularity logo, Celularity IMPACT, Biovance, Biovance 3L, Interfyl, Lifebank, CentaFlex and other trademarks or service marks of Celularity Inc. appearing in this annual report are the property of Celularity Inc. This annual report on Form 10-K also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing herein are the property of their respective holders.

## **SUMMARY RISK FACTORS**

Our business involves significant risks. Below is a summary of the material risks that our business faces, which makes an investment in our securities speculative and risky. This summary does not address all these risks. These risks are more fully described below under the heading “Risk Factors” in Part I, Item 1A of this annual report on Form 10-K. Before making investment decisions regarding our securities, you should carefully consider these risks. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such event, the market price of our securities could decline, and you could lose all or part of your investment. In addition, there are also additional risks not described below that are either not presently known to us or that we currently deem immaterial, and these additional risks could also materially impair our business, operations or market price of our Class A common stock.

- We have incurred net losses in every period since our inception, have no cellular therapeutic candidates approved for commercial sale and we anticipate that we will incur substantial net losses in the future. There is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to curtail our operations. We will need to raise additional capital to support our operations. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital or address our liquidity needs may force us to delay, limit or terminate our operations, make further reductions in our workforce, discontinue our commercialization efforts for our biomaterials products as well as other clinical trial programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.
- We are currently required to make cash payments under our pre-paid advance agreement with YA II PN, Ltd., or Yorkville, and may not have sufficient cash available when due. If we fail to pay Yorkville when due, Yorkville could deem such non-payment an event of default under our pre-paid advance agreement and accelerate repayment of amounts advanced under the agreement, which would impact our liquidity, require us to modify our operations to meet any prepayment obligations and could force us to seek protection under the provisions of the U.S. Bankruptcy Code.
- Our placental-derived cellular therapy candidates represent a novel approach to cancer, infectious and degenerative disease treatments that creates significant challenges.
- Our business is highly dependent on the success of our lead therapeutic candidates. If we are unable to obtain regulatory approval for our lead candidates and effectively commercialize our lead therapeutic candidates for the treatment of patients in approved indications, our business would be significantly harmed.
- We rely on distribution arrangements for the sale of our biomaterials products. We may incur costs to meet demand forecasts that do not materialize or we may be unable to meet demand if our distribution partners do not provide adequate forecasts.
- Our commercial biomaterials business may be impacted if regulatory authorities determine that certain of our products that are, or are derived from, human cells or tissues do not qualify for reimbursement. For example, during 2022, the Center for Medicare & Medicaid Services, or CMS, began rejecting claims for Interfyl submitted by one of our distribution partners, which has not yet been resolved.
- We rely on CAR-T viral vectors from Sorrento Therapeutics, Inc., or Sorrento, for our CYCART-19 therapeutic candidate and termination of this license, or any future licenses, could result in the loss of significant rights, which would harm our business. In February 2023, Sorrento announced that it commenced voluntary proceedings under Chapter 11 of the U.S. Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of Texas. At this time, we cannot predict what impact the bankruptcy will have on Sorrento’s continued ability to perform under the license agreement.
- We rely and will continue to 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, we may not be able to obtain regulatory approval of, or commercialize, our therapeutic candidates.
- The U.S. Food and Drug Administration, or FDA, regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory of our therapeutic candidates.
- We may not be able to file Investigational New Drug, or IND, applications to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed without additional information or at all, and if so, we may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect. For example, we submitted an IND for CYCART-19 in the first quarter of 2022 and FDA requested additional information before we could proceed with the clinical trial, and we continue to respond to FDA information requests before being able to proceed.

- We operate our own manufacturing and storage facility, which requires significant resources; manufacturing or other failures could adversely affect our clinical trials and the commercial viability of our therapeutic candidates and our biobanking and degenerative diseases businesses. We may not be successful in our plan to leverage our core expertise in cellular therapeutic development and manufacturing to generate revenues by providing contract manufacturing and development services to third parties.
- We rely on donors of healthy human full-term post-partum placentas to manufacture our therapeutic candidates and biomaterials products, and if we do not obtain an adequate supply of such placentas from qualified donors, development of our placental-derived allogeneic cells may be adversely impacted.
- Our clinical trials may fail to demonstrate the safety and/or efficacy of any of our therapeutic candidates, which would prevent or delay regulatory approval and commercialization.
- If our effort to protect the proprietary nature of the intellectual property related to our technologies are inadequate, we may not be able to compete effectively in our market.
- We are, and in the future may be, party to agreements with third parties. Disputes may arise with such third parties regarding the terms of such agreements, including terms governing payment obligations, contractual interpretation, or related intellectual property ownership or use rights, which could materially adversely impact us, including by requiring the payment of additional amounts, or requiring us to invest time and money in litigation or arbitration.
- Our therapeutic 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.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- Our relationship with customers, physicians, and third-party payors are subject to numerous laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.
- Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic and future outbreaks of the disease, in regions where we or third parties on which we rely have concentrations of clinical trial sites or other business operations.
- We will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to various compliance initiatives.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this annual report on form 10-K constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Forward-looking statements relate to expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar expressions concerning matters that are not historical facts. These statements relate to our future events, including our anticipated operations, research, development and commercialization activities, clinical trials, operating results and financial condition. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- the success, cost, timing and potential indications of our cellular therapy candidate development activities and clinical trials, as well as our ability to expand our biomaterials business and leverage our core expertise in cellular therapeutic development and manufacturing to generate revenues by providing contract manufacturing and development services to third parties;
- the timing of the initiation, enrollment and completion of planned clinical trials in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval of our therapeutic candidates in any of the indications for which we plan to develop them, and any related restrictions, limitations, and/or warnings in the label of any approved therapeutic;
- our ability to obtain funding for our operations, including funding necessary to complete the clinical trials of any of our therapeutic candidates;
- our ability and plans to research, develop, manufacture and commercialize our therapeutic candidates, as well as our degenerative disease products;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- the size of the markets for our therapeutic candidates and biomaterials products, and our ability to serve those markets;
- our ability to successfully commercialize our therapeutic candidates and biomaterials products;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- our expenses, future revenues, capital requirements and needs for additional financing;
- our use of cash and other resources; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our therapeutic candidates, degenerative disease products, and our ability to operate our business without infringing on the intellectual property rights of others.

In some cases, you can identify these forward-looking statements by the use of terminology such as “anticipate,” “believe,” “can,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “forecast,” “intends,” “may,” “might,” “outlook,” “plan,” “possible,” “potential,” “predict,” “project,” “seek,” “should,” “strive,” “target,” “will,” “would” and the negative version of these words or other comparable words or phrases, but the absence of these words does not mean that a statement is not forward-looking. These statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this annual report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

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 on Form 10-K and the documents that we reference in this annual report on Form 10-K 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 do not plan 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. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this annual report on Form 10-K.

## PART I

### Item 1. Business.

#### Overview

We are a clinical-stage biotechnology company leading the next evolution in cellular medicine by developing off-the-shelf placental-derived allogeneic cell therapies for the treatment of cancer and immune and infectious diseases. We are developing a pipeline of off-the-shelf placental-derived allogeneic cell therapy product candidates including T cells engineered with a chimeric antigen receptor, or CAR, natural killer, or NK, cells, mesenchymal-like adherent stromal cells, or MLASCs, and exosomes. These therapeutic candidates target indications across cancer, infectious and degenerative diseases. We believe that by harnessing the placenta's unique biology and ready availability, we will be able to develop therapeutic solutions that address a significant unmet global need for effective, accessible and affordable therapeutics. We also actively develop and market biomaterial products derived from the placenta. Prior to 2023, we marketed those products domestically primarily serving the orthopedic and wound care markets. We now intend to market placental biomaterials outside of the United States with an initial focus on markets in the Middle East and North Africa. Our biomaterials business today is comprised primarily of the sale of our Biovance and Interfyl products, directly or through our distribution network. Biovance is decellularized, dehydrated human amniotic membrane derived from the placenta of a healthy, full-term pregnancy. It is an intact, natural extracellular matrix that provides a foundation for the wound regeneration process and acts as a scaffold for restoration of functional tissue. Interfyl is human connective tissue matrix derived from the placenta of a healthy, full-term pregnancy. It is used by a variety of medical specialists to fill soft tissue deficits resulting from wounds, trauma, or surgery. We are developing new placental biomaterial products to deepen the commercial pipeline beyond Biovance and Interfyl. We also plan to leverage our core expertise in cellular therapeutic development and manufacturing to generate revenues by providing contract manufacturing and development services to third parties. The initial focus of this new service offering will be to assist development stage cell therapy companies with the development and manufacturing of their therapeutic candidates for clinical trials. In January 2023, we announced reprioritization of efforts which resulted in a reduction of approximately one-third of our workforce as of March 2023.

Our Celularity IMPACT platform capitalizes on the benefits of placenta-derived cells to target multiple diseases, and provides seamless integration, from bio sourcing through manufacturing cryopreserved and packaged allogeneic cells, in our purpose-built U.S.-based 147,215 square foot facility. We believe the use of placental-derived cells, sourced from the placentas of full-term healthy informed consent donors, has potential inherent advantages, from a scientific and an economic perspective. First, relative to adult-derived cells, placental-derived cells demonstrate greater stemness, meaning the ability to expand and persist. Second, placental-derived cells are immunologically naïve, meaning the cells have never been exposed to a specific antigen, and suggesting the potential for less toxicity and for low or no graft-versus-host disease, or GvHD, in transplant. Third, our placental-derived cells are allogeneic, meaning they are intended for use in any patient, as compared to autologous cells, which are derived from an individual patient for that patient's sole use. We believe this is a key difference that will enable readily available off-the-shelf treatments that can be delivered faster, more reliably, at greater scale and to more patients.

From a single source material, the postpartum human placenta, we derive five allogeneic cell or extracellular vesicle types: T cells, unmodified NK cells, genetically modified NK cells, MLASCs and exosomes, which are used in seven key cell therapeutic programs—CYCART-19, CYCART-201, CYNK-001, CYNK-301, CYNK-302, APPL-001, and pEXO-001. CYCART-19 is a placental-derived CAR-T cell therapy, in development for the treatment of B-cell malignancies, initially targeting the cluster of differentiation 19, or CD19, receptor, the construct and related CARs for which are in-licensed from Sorrento. In the first quarter of 2022, we submitted an IND to investigate CYCART-19 for treatment of B-cell malignancies and in late May 2022, received formal written communication from FDA requesting additional information before we can proceed with the planned Phase 1/2 clinical trial. We are in the process of working with the FDA in an effort to resolve its questions as promptly as possible. We expect to commence the trial, if the IND is cleared by FDA, and sufficient funding is available, in second half of 2023. We will also progress CYCART-201, our genetically modified T-cell expressing CD16 with a T-cell receptor, or TCR, knockout in combination with monoclonal antibodies, or mAbs, in non-Hodkin's lymphoma, or NHL, and in solid tumors. CYNK-001 is a placental-derived unmodified NK cell. In 2022, we had active and approved clinical trials under development for the treatment of acute myeloid leukemia, or AML, a blood cancer, and for glioblastoma multiforme, or GBM, a solid tumor cancer. CYNK-001 is currently in an active Phase 1 trial for AML. We will also advance CYNK-301 as our next generation CAR-NK that has the potential to overcome some of the challenges faced by NK therapies in treating relapse refractory AML, or rAML. Due to a need to prioritize corporate resources, in January 2023 we announced our intention to cease recruitment in the GBM trial. We will however, continue to advance our solid tumor research programs. CYNK-302 is a next generation CAR-NK being developed in solid tumors with an initial focus on non-small cell lung cancer, or NSCLC, an area of continued high unmet need. APPL-001 is a placenta-derived MLASC being developed for the treatment of Crohn's disease, and other degenerative diseases. pExo-001 is placenta-derived exosome being developed for the treatment of osteoarthritis.

Our Celularity IMPACT manufacturing process is a seamless, fully integrated process designed to optimize speed and scalability from the sourcing of placentas from full-term healthy informed consent donors through the use of proprietary processing methods, cell



selection, product-specific chemistry, manufacturing and controls, or CMC, advanced cell manufacturing and cryopreservation. The result is a suite of allogeneic inventory-ready, on demand placental-derived cell therapy products. We also operate and manage a commercial biobanking business that includes the collection, processing and cryogenic storage of certain birth byproducts for third-parties.

Our current science is the product of the cumulative background and effort over two decades of our seasoned and experienced management team. We have our roots in Anthrogenesis Corporation, or Anthrogenesis, a company founded under the name Lifebank in 1998 by Robert J. Hariri, M.D., Ph.D., our founder and Chief Executive Officer, and acquired in 2002 by Celgene Corporation, or Celgene. The team continued to hone their expertise in the field of placental-derived technology at Celgene through August 2017, when we acquired Anthrogenesis. We have a robust global intellectual property portfolio comprised of over 1,500 patents and patent applications protecting our Celularity IMPACT platform, our processes, technologies and current key cell therapy programs. We believe this know-how, expertise and intellectual property will drive the rapid development and, if approved, commercialization of these potentially lifesaving therapies for patients with unmet medical needs.

## **Our Pipeline**

Leveraging our Celularity IMPACT platform, we have four placental-derived allogeneic cell types: T cells, or pT, unmodified NK cells (CYNK-001), genetically modified NK cells (CYNK-301, CYNK-302) and MLASCs. We are also researching a placenta-derived adherent cell exosome, or pEXO.

While we continue to prosecute the Phase 1 trial of CYNK-001 in minimal residual disease positive, or MRD+ve, and rrAML, we are also progressing our next generation modified NK platform in both rrAML and solid tumors.

CYNK-301 is a next generation CAR-NK that has the potential to overcome some of the challenges faced by NK therapies in treating rrAML including minimizing the burden of lymphodepletion, while optimizing proliferation, persistence and efficacy. CYNK-301 incorporates membrane bound Interleukin 15, or IL15, to enhance NK cell activation, proliferation and persistence, with additionally, marrow homing and a targeted CAR to further enhance efficacy.

CYNK-302 is a CAR-NK being developed in solid tumors with an initial focus on NSCLC, an area of continued high unmet need. CYNK-302 is a next-generation construct building on our learning from CYNK-101. It is genetically modified to express CD16 and is further enhanced by incorporating membrane bound IL15 and an undisclosed targeted CAR.

We continue to progress our CYCART-19 program towards clinical trials and continue to develop our T-Cell platform with potentially first-in-class or best-in class constructs. CYCART-201 is designed for use in combination with multiple potential mAbs with broad therapeutic potential. CYCART-201 is genetically modified to express CD16 with a TCR knockout. Our initial hematological development will be in NHL and our solid tumor development in human epidermal growth factor receptor 2 positive, or HER2+ve, tumors, both in combination with targeted mAbs.

Following a strategic review, we have refocused on the development of our autoimmune and degenerative disease assets. APPL-01 is a genetically modified MLASC which is being initially investigated in Crohn's disease, or CD, in order to build on the encouraging signals seen in our previous trials of unmodified MLASC in CD. We will continue to progress pEXO in osteoarthritis which continues to have significant unmet need and market potential.

Hematological Malignancies	Platform	Functionality	Indication	PRE-CLINICAL		CLINICAL	
				Discovery	IND-Enabling	Phase 1/2	Phase 2/3
CYNK-001	pNK	Unmodified	AML				
CYNK-301	pNK	IL15 + Marrow Homing + CAR	AML				
CYCART-19	pT	CD19 + TCR KO	NHL, MCL				
CYCART-201	pT	CD16 + TCR KO + mAb	NHL, MCL				
Solid Tumor	Platform	Functionality	Indication	Discovery	IND-Enabling	Phase 1/2	Phase 2/3
CYCART-201	pT	CD16 + TCR KO + mAb	HER2+ Tumors				
CYNK-302	pNK	CD16 + IL15 + CAR	NSCLC				
Autoimmune & Degenerative Disease	Platform	Functionality	Indication	Discovery	IND-Enabling	Phase 1/2	Phase 2/3
APPL-101	MLASC	TF KO	Crohn's Other potential indications				
pEXO-001	pEXO	Unmodified	Osteoarthritis				

TCR KO = T-cell receptor knock out, TF KO = tissue factor knock out, MCL = mantle cell lymphoma

Further, we are looking to expand our pipeline of placentally derived biomaterial products.

Degenerative Diseases	Indication	Discovery	Regulatory		Brands
Placental Connective Tissue Matrix	Integumental Tissue Replacement		361 HCT/P		Interfyl®
Amniotic Membrane Allograft	Wound Covering		361 HCT/P		BIOVANCE®
Tri-Layer Amniotic Membrane Allograft	Wound Covering		361 HCT/P		3L
Tri-Layer Amniotic Membrane Allograft	Protective Cover		361 HCT/P		Biovance3L OCULAR
Placental Matrix	Tendon				
Placental Matrix	Bone, Spine, Dental				
Degenerative Diseases	Indication	Preclinical	Regulatory	Phase 1	Phase 2
Placental Matrix	Aesthetics				
Placental Matrix	Osteoarthritis				

## Celularity IMPACT Platform

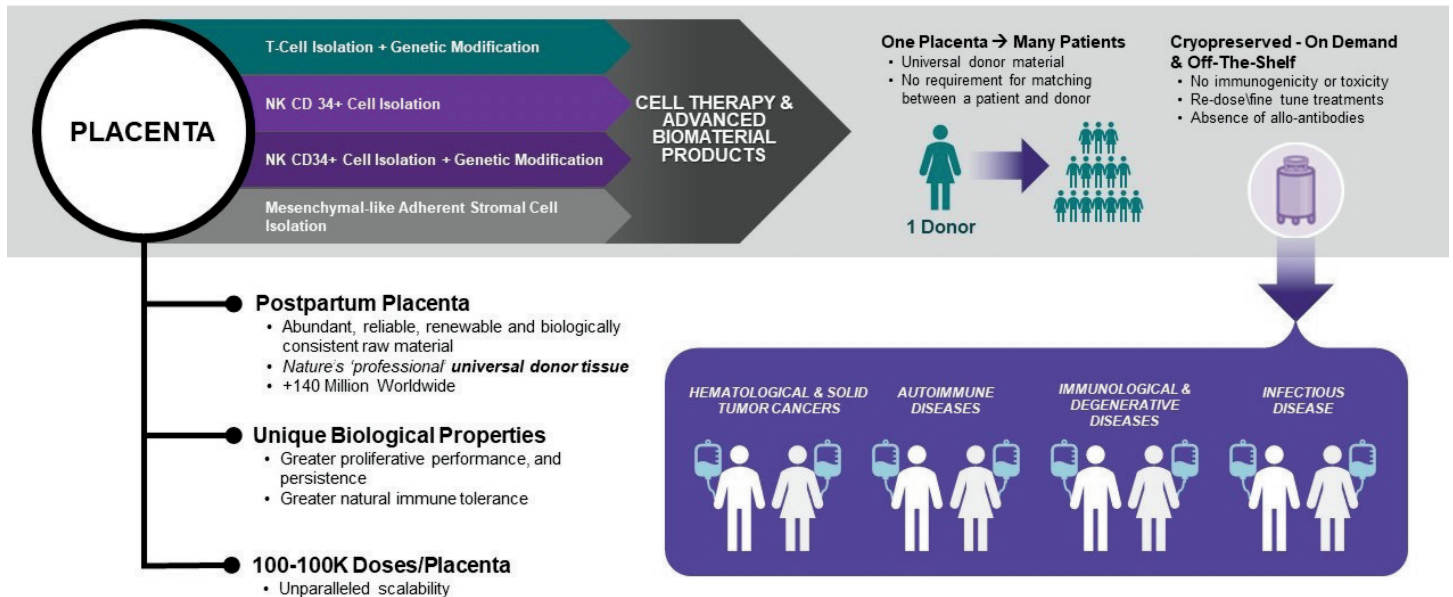
Placental-derived cell therapies offer potentially lifesaving therapies for patients with unmet medical needs. We have developed and acquired proprietary technology for collecting, processing and storing placental stem cells with potentially broad therapeutic applications across cancer, infectious and degenerative diseases.

We use our proprietary Celularity IMPACT platform for the development of **Immuno-Modulatory Placenta-derived Allogeneic Cell Therapies**. We believe that by harnessing the placenta's unique biology and ready availability, we will be able to develop therapeutic solutions that address a significant unmet global need for effective, accessible and affordable therapeutics.

Our Celularity IMPACT manufacturing process is a seamless, fully integrated process that is built to optimize speed and scale from sourcing of human full term healthy postpartum donated placentas through proprietary processing methods, cell selection, product-

specific CMC, advanced cell manufacturing and cryopreservation and result in allogeneic inventory-ready and on demand placental-derived cell therapy products. The fully integrated process is housed in our purpose-built manufacturing, translational research and biobanking facility.

Our Celularity IMPACT platform capitalizes on our integrated processes and the unique biologic characteristics of placenta-derived allogeneic cells to target multiple diseases including indications across cancer, infectious and degenerative diseases. The platform is designed to accelerate the speed at which therapies can be provided to patients while ensuring manufacturing excellence of high quality and pure placental-derived cell therapy products at a lower cost of revenues. We believe cell therapy inventory should be available to physicians on demand to treat patients in need and to enable repeat dosing regimens that other cell therapy platforms will not be able to support.



## Our Strategy

Our goal is to lead the next evolution in cellular medicine by delivering off-the-shelf allogeneic cellular therapies, at greater scale and quality with attractive economics. We believe achieving this goal will result in placental-derived allogeneic cell therapies becoming a standard of care in various indications across cancer, infectious and degenerative diseases, and enable us to make potentially lifesaving therapies more readily accessible to more patients throughout the world. We plan to achieve this mission by:

- Leveraging the inherent advantages of placental-derived cells.** Our cells come from the postpartum placenta donated by healthy donors who have signed an informed consent, representing a renewable, economical and highly scalable starting material collected under rigorous controls. We use those cells to produce on-demand, off-the-shelf investigational allogeneic cellular therapy products investigational medicines that are designed to sidestep treatment delays inherent to more costly autologous cell therapies and other allogeneic cell therapy approaches, all while offering the potential for greater in vivo expansion, persistence, potency and acceptance. Further, we believe the immunological naïveté of placental cells may allow for potentially less toxicity.
- Capturing efficiencies through our integrated Celularity IMPACT platform.** Manufacturing allogeneic cell therapeutic candidates involves a series of complex and precise steps. We believe a critical component to our success will be to leverage our rapidly scalable, end-to-end supply chain. Applying proprietary manufacturing know-how, expertise and capacity utilizing our purpose-built U.S.-based current good manufacturing practices, or cGMP, compliant facility, we believe our fully integrated manufacturing operations and infrastructure will allow us to improve the manufacturing process, eliminate reliance on contract manufacturing organizations, or CMOs, and more rapidly advance therapeutic candidates. We also plan to leverage this core expertise to generate revenues by providing contract manufacturing and development services to third parties.
- Selectively targeting indications with unmet patient need with potential for accelerated development.** Our pipeline reflects our intent to leverage the unique biology of the placenta to develop placental-derived allogeneic cells for indications where the demonstrated properties of such cells could provide an advantage, both in terms of development (sourcing and



proliferation) and potential efficacy (affinity). In selecting indications, we evaluate where the biological properties of placental-derived cells position them for success, as well as where there is a clearly defined regulatory pathway providing the potential for accelerated development to address unmet patient need.

- ***Growing our existing commercial business and deepening the pipeline of placentally derived biomaterial products.*** We intend to grow our existing commercial business both through higher volumes of product sold through existing domestic distribution relationships as well as initiate new distribution relationships outside of the United States. Our initial efforts to grow outside the United States will focus on distribution relationships in the Middle East and North Africa. We are continuing to invest in new biomaterials programs, some or all of which may require different regulatory pathways than Section 361 HCT/Ps. We are currently developing a tendon wrap indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. We are also developing a bone void filler product for use in orthopedic surgical markets. We have preliminary data from a knee osteoarthritis animal model that placentally derived extracellular matrix may decrease joint pain and promote chondrogenesis in damaged cartilage.
- ***Continuing to invest in basic and translational research.*** We intend to continue to invest in the discovery and development of additional pipeline cell franchises and explore other placental-derived cell opportunities. Preclinical and early clinical data demonstrating the unique biological activity and potential of placental-derived stem cells, provide potential for multiple highly effective cell therapy programs.
- ***Benefiting from collective experience of deep, seasoned management team.*** We have a deep, seasoned management team with experience in all aspects of cellular medicine, including discovery and translational research, clinical development and product approval, manufacturing and process development and commercialization. For over two decades, the team has been at the vanguard of cellular medicine, and has collectively seen a number of programs, including one cell therapy, through FDA-approval to commercialization.

## **Our Team and Corporate History**

### ***Anthrogenesis Corporation***

We have our roots in Anthrogenesis, a corporation founded under the name Lifebank in 1998 by Robert J. Hariri, M.D., Ph.D., our founder and Chief Executive Officer. Like us, Anthrogenesis was focused on developing and delivering cellular therapies using placental-derived stem cells for the treatment of cancers, degenerative and infectious diseases. Celgene acquired Anthrogenesis in December 2002 in a stock-for-stock merger, and operated Anthrogenesis as Celgene Cellular Therapeutics, or CCT, a wholly-owned subsidiary of Celgene. Similarly, CCT continued to focus on the research and development of placental-derived stem cells. In 2016, Dr. Hariri formed Celularity and began acquiring the assets that form our business today. These include our degenerative disease and biobanking businesses, which Celgene had sold to Human Longevity, Inc., or HLI, a genomic-based health intelligence company co-founded by Dr. Hariri and Dr. Diamandis, one of our directors, as well as our core cellular therapeutics business, which we acquired in August 2017, when we acquired Anthrogenesis from Celgene in exchange for stock and event-driven contingent value rights, or CVRs.

### ***Celgene Corporation (acquired by Bristol Myers Squibb)***

#### ***License Agreement***

In August 2017, in connection with the Anthrogenesis acquisition, we entered into a license agreement with Celgene. Pursuant to the license with Celgene, we granted Celgene a worldwide, royalty-free, fully-paid up, non-exclusive license under Anthrogenesis' intellectual property in existence as of the date of the Celgene license or as developed by Celgene in connection with any transition services activities related to the merger for preclinical research purposes, as well as to develop, manufacture, commercialize and fully exploit products and services that relate to the construction of any CAR, the modification of any T-cell or NK cell to express such a CAR, and/or the use of such CARs or T-cells or NK cells for any purpose, which commercial license is sublicensable. Either party may terminate the Celgene license upon an uncured material breach of the agreement by the other party or insolvency of the other party.

#### ***Contingent Value Rights***

In August 2017, in connection with the Anthrogenesis acquisition, we issued shares of our Series X Preferred Stock to Celgene as merger consideration and entered into the contingent value agreement with Celgene, or the CVR Agreement. Pursuant to the CVR Agreement, we issued one CVR in respect of each share of Series X Preferred Stock issued to Celgene in the acquisition. Such CVRs are not separable from the shares of Series X Preferred Stock other than in an initial public offering or a sale of our company.

The CVR Agreement entitles the holders of the CVRs to an aggregate amount, on a per program basis, of \$50 million in regulatory milestones and an aggregate \$125 million in commercial milestone payments with respect to certain of our investigational therapeutic programs, which would include the current CYNK-001, CYNK-101 and PDA-002 pipeline candidates and the legacy PDA-001 program

(a placenta-derived adherent cells, proprietary to Anthrogenesis, that is formulated for intravenous delivery) that are no longer in development. Such payments under the CVR Agreement also expressly cover PNK-007 (which includes certain NK cells proprietary to Anthrogenesis, produced by a process proprietary to Anthrogenesis as of the closing of the Anthrogenesis transaction) and certain PNK-007 cells with a genetic modification (but not including NK cells with a chimeric receptor, including a CAR), along with any derivatives, parts, subparts, or progeny of any of the foregoing, or any therapeutic based or derived (in whole or in part) on certain related development programs as they existed as of the closing of the Anthrogenesis transaction. Accordingly, as we expand our NK cell type franchise into new indications and, as a general matter, because these payments are not payable until a later stage of development, we expect to continue to evaluate our present and future therapeutic candidates as they develop and evolve in light of the specific terms in the CVR Agreement to determine the specific therapeutics on which such amounts will be payable. In addition, with respect to each such program and calendar year, the CVR holders will be entitled to receive a royalty equal to a mid-teen percentage of the annual net sales for such program's therapeutics from the date of the first commercial sale of such program's therapeutic in a particular country until the latest to occur of the expiration of the last to expire of any valid patent claim covering such program therapeutic in such country, the expiration of marketing exclusivity with respect to such therapeutic in such country, and August 2027 (i.e., the tenth anniversary of the closing of the acquisition of Anthrogenesis). No payments under the CVR Agreement have been made to date.

#### *Investors' Rights Agreement and Investment Rights Agreement*

We also entered into an investors' rights agreement and an investment rights agreement, each with Celgene and certain other parties thereto in August 2017 in connection with the Anthrogenesis acquisition. For more information regarding these agreements, see Item 13 "*Certain Relationships and Related Transactions, and Director Independence — License and Other Agreements*" of this annual report.

### **Allogeneic Placental-Derived Cells**

#### ***Biomaterials Collection***

The initial source material for our four allogeneic cell types is the postpartum human placenta. We source human placental birth material used for the manufacture of our products from accredited hospitals and birth centers, with collections performed by licensed health care professionals. Eligibility for donation is determined by a donor screening process that includes education about the donor program, obtaining informed consent from the donor and completion of a detailed maternal health questionnaire and family health history. These forms are completed by the donor, with assistance from trained collection technicians as needed. Donors providing birth materials do not encounter any fees and are not remunerated.

Licensed health care professionals collect donor material utilizing our proprietary collection kits, which include barcode labels for biomaterials (cord blood, placenta and maternal blood samples) along with appropriate chain of custody documentation. Once collected, the donated material and a maternal blood sample are shipped in an insulated container via courier to our Florham Park, New Jersey laboratory and manufacturing facility.

Upon arrival at our facility, the donated material is reviewed for labeling completeness and accuracy of the barcoded kit and is electronically coded into a validated software database. If all quality criteria are met, the donated material is then individually evaluated and forwarded to the appropriate production suite for processing and manufacturing. We believe that our sourcing is rapidly scalable due to numerous established procurement relationships that provide a constant renewable supply to meet current and future manufacturing needs.

#### ***Unique Biology of Placenta-Derived Cells***

Placental-derived cells have unique biology related to immunological naïveté, stemness, persistence and proliferation that makes them a biologically preferred starting material with the potential for less toxicity and superior biological activity relative to adult bone marrow or peripheral blood-derived cells.

Research has shown that the human placenta is a novel and valuable source of multipotential stem/progenitor cells of mesenchymal and hematopoietic origin, which have multiple therapeutic applications. Our characterization data show that approximately one to five percent of placental-derived cells are CD34+ hematopoietic stem cells, or HSCs, among which expression of certain markers suggests that such HSCs have more self-renewal capacity and the potential to facilitate the early engraftment of the placental-derived cells. In addition, further characterization has shown low T-cell content and immature T subpopulations. This demonstrated immunological naïveté further suggests the potential for low or no graft vs host disease, or GvHD, in transplant. Furthermore, mesenchymal-like cells have been shown to possess other characteristics, capabilities and effects (e.g., osteogenic, chondrogenic, adipogenic differentiation capabilities and immunomodulatory effects). The high quantity of mesenchymal-like cells and Treg cells indicate that placental-derived cells can potentially contribute to prevention of GvHD and host microenvironment modulation. In summary, we believe the stemness,

potential capacity of proliferation and persistence of placental-derived cells support multiple potential therapeutic applications, including those in development by us.

We are also researching placental-derived exosomes for potential therapeutic applications. Exosomes are a kind of extracellular vesicle that act as communication channels between cells and cause functional changes in recipient cells. Exosomes enable intercellular communication by transferring specific cargo contents to a recipient cell and can confer epigenetic changes in the recipient cells by delivering microRNAs, or miRNAs. Exosomes have been identified as the primary factors responsible for paracrine effects detected in all types of stem cells and for the transfer of genetic material from stem cells to the tissue-specific cell that needs regeneration. Exosomes have been shown to possess powerful regenerative potential, including immune-modulatory properties and anti-inflammatory properties. We discovered a type of exosome that we call pEXO. Rich in growth factors, deoxyribonucleic acid, or DNA, fragments, miRNAs, and messenger RNAs, pEXO exhibit particular markers that distinguish them from other exosomes that are not derived from placenta-derived adherent cells. We are investigating purified pEXO formulated into pharmaceutical compositions for human administration to promote angiogenesis and/or vascularization, to modulate immune activity and to repair tissue damage.

### ***Overview of CAR-T Cells***

White blood cells are a component of the immune system and responsible for defending the body against infectious pathogens and other foreign material. T cells are a type of white blood cell and are involved in both sensing and killing infected or abnormal cells, including cancer cells, as well as coordinating the activation of other cells in an immune response.

Unlike adult peripheral blood mononuclear cell, or PBMC, derived T cells, placental-derived T cells are mostly naïve and can be readily expanded while maintaining an earlier differentiation phenotype, such as greater expression of naïve/memory markers and lower expression of effector/exhaustion markers. These characteristics allow for greater proliferative potential of these cells *ex vivo*. Placental-derived T cells are also known to have greater immune tolerance and display impaired allogeneic activation, contributing to lower incidences of severe GvHD, which makes them an attractive cell population for use as an allogeneic, adoptive cell therapy. We have developed a robust process for the isolation, transduction and expansion of placental-derived T cells to generate “off-the-shelf” allogeneic CAR-T cells.

Allogeneic human placental T cells are derived from healthy donor placentas. We separate out mononuclear cells using a mononuclear cell separation method to isolate placental T cells prior to cryopreservation. Our allogeneic CAR-T cell product begins with the thawing and activation of the isolated placental T cells, followed by viral transduction of the cancer-targeting CAR construct and an additional genetic modification step to minimize any risk of GvHD. Once transduced and transfected, the CAR-T cells are expanded to yield large quantities of these cells prior to harvest, final formulation and cryopreservation of the cellular therapeutic.

### ***Overview of NK cells — Unmodified and Genetically Modified***

NK cells are potent effector cells of the innate immune system responsible for identifying and eliminating abnormal and stressed host cells. They are equipped with NK cell-specific activating receptors that recognize conserved antigens induced by cellular stress while being simultaneously tuned with inhibitory receptors to avoid mistakenly targeting healthy cells. NK cells are particularly relevant in combating viral infections and mediating anti-tumor immunity in which normal cellular processes are stressed for the purposes of perpetuating viral infection and cancer cell proliferation.

Commercializing NK cell therapies has been limited by the difficulty and cost to scale the production of mature NK cells for clinical dosing. Utilizing our Celularity IMPACT platform, our proprietary process has mitigated these limitations by expanding and differentiating placental-derived stem cells into NK cells over a period of 35 days. We derive the HSCs from healthy donor placentas, then propagate and differentiate these cells into NK cells. This process can produce hundreds of doses per donor placenta. We also developed technologies that can achieve high genetic modification efficiency by transducing placenta HSCs and producing downstream stable gene modified CYNK cells with enhanced cancer killing activities. These cells are then cryopreserved and available to be shipped upon request.

For our genetically modified NK cells, our allogeneic modified NK cell product begins with the thawing and activation of the isolated placental NK cells. We then use a lentiviral vector transduction to augment the effector functions of the NK cells and to sustain their tumor-killing properties. We believe that our genetically modified NK cells can be used in combination with therapeutic mAbs to boost antibody-dependent cellular cytotoxicity, or ADCC, potential.

### ***Overview of MLASCs***

Placental-derived MLASCs are a novel, culture-expanded mesenchymal-like cell population derived from placental tissue. *In vivo*, we demonstrated that MLASCs’ immune-modulatory properties alleviate autoimmunity and possess anti-inflammatory activity. Both intravenous and intramuscular administration formulations of the first generation of MLASCs have been developed and investigated in

clinical studies in Crohn's Disease, multiple sclerosis, rheumatoid arthritis, stroke, diabetic foot ulcers and diabetic peripheral neuropathy. We are developing next generation genetically modified MLASCs for the treatment of degenerative diseases.

Allogeneic human placental MLASCs are derived from healthy donor placentas. Our allogeneic MLASC product begins with the thawing and activation of the isolated placental-derived MLASCs, followed by genetic modification of tissue factor to reduce potential toxicities and lower risk of adverse effects. Once modified, we expand the MLASCs to large quantities prior to harvest, final formulation and cryopreservation of the cellular therapeutic.

### ***Overview of Exosomes***

Exosomes are acellular, nano-size lipid bilayer membrane particles released by cells into extracellular space and play important roles in cell to cell, tissue to tissue and organ to organ communications. Exosomes are generated from late endosomes with 30-200 nanometers in diameter. When fused with the targeted cells, the molecular cargos (proteins, lipids, DNAs, mRNAs, and microRNAs) exosomes carry are inserted into the cells to exert the functions.

Recently, exosomes are being recognized as promising candidates in the treatment of degenerative diseases. Evidence has suggested that part of the observed cell therapeutic effects is mediated by exosomes. Exosome therapy has certain advantages over cell therapy such as: low/non-immunogenicity, easy storage, and administration. In addition, due to their nano-size, exosomes can cross the brain-blood barrier and can be delivered to broader target tissues and organs than cell-based therapeutics.

pExo-001 is a human postpartum placenta derived exosome product which consists of cytokines, chemokines, and growth factors that have been reported to have regenerative and immuno-regulatory activities.

### ***Allogeneic Cell Therapies — an “Off-the-Shelf” Approach***

There are two primary approaches to engineered cell therapies: autologous and allogeneic. Autologous therapies use engineered cells derived from the individual patient, while allogeneic therapies use cells derived from an unrelated third-party healthy donor. We believe our human placental-derived allogeneic platform is leading the next evolution of cellular medicine because we aim to deliver off-the-shelf allogeneic cellular therapies, at greater scale and quality with attractive economics, potentially making lifesaving therapies more readily accessible to more patients throughout the world.

Our human placenta-derived allogeneic platform currently includes placental CAR-T cells (CYCART-19 and CYCART-201), NK cells (CYNK-001, CYNK-301 and CYNK-302), MLASCs (APPL-001) and exosomes (pEXO-001).

#### ***CYCART***

Currently, autologous CAR-T products are manufactured by isolating T cells from the patient's blood through a process known as leukapheresis. The cancer-targeting construct expressing specific CAR proteins is virally transduced into the T cells and the engineered T cells are then propagated until a sufficient number are available for infusion. The engineered T cells are then shipped back to the clinical center for administration to the patient. The process from leukapheresis to delivery to the clinical center takes approximately four weeks. While the autologous approach has been revolutionary, demonstrating compelling efficacy in many patients, we are burdened by lengthy vein-to-vein time, high production cost, variable potency and manufacturing failures.

Conversely, our allogeneic placental-derived T cells are derived from healthy donors that have undergone rigorous donor screening and selection. Manufactured drug product can be deployed to patients immediately in sufficient quantities because administration is not limited by patient cell sourcing and individual drug product expansion. As an “off-the-shelf” treatment, CYCART cells also offer the potential to re-dose patients, if necessary. Healthy births are in hundreds of millions worldwide, and the placenta provides an abundant, renewable source of healthy, ready to use lymphocytes. In addition, placental-derived T cells contain an abundance of stem cell memory T cells, which confer high proliferation and durability. Placental T cells are known to be immune-privileged and have low donor to host toxicity (GvHD). We are therefore potentially a generally safer cell population. Furthermore, allogeneic placental T cells can be genetically engineered to minimize the risk of GvHD and avoid being destroyed by the patient's immune system. Therefore, CYCART cells may possess an advantageous safety profile while delivering effective tumor eradication activity and durable persistence in patients.

#### ***CYNK***

Similarly, autologous NK cells and genetically modified autologous NK cells have been used in the setting of immuno-oncology. NK cells can directly kill cancer cells by recognizing signals of cellular stress and carry no risk of GvHD. However, autologous peripheral blood derived NK cells have limited proliferation capacity and usually require leukemia cell line-based technology to assist production. In addition, autologous CAR-NK was shown to encounter technical challenges due to low transduction efficiency of CAR vectors in the peripheral NK cells. Our NK platform propagates placenta derived HSCs and differentiates these cells into NK cells (CYNK). This process can produce hundreds of doses per placenta donor. We have also developed technologies that can achieve high



genetic modification efficiency by transducing placenta HSCs and produce downstream stable gene modified CYNK cells with enhanced cancer killing activities. These cells are then frozen and can be shipped to clinical administration immediately upon request.

### MLASCs

Both autologous and allogeneic bone marrow or adipose tissue derived MLASCs have been used in human clinical trials. Autologous MLASC therapies have advantages including the absence of donor cell related adverse events and fewer regulatory hurdles since cell products are derived from a donor's own cells. However, autologous MLASC products carry the inherited or aging-related biological defects from the donor, which may impair therapeutic value. Furthermore, in most cases, autologous cells still require cultivation before patient administration and there is a risk of manufacturing failure.

Conversely, allogeneic MLASCs can provide an off-the-shelf product with high quality and flexibility of dosing. MLASCs are regarded as immune-privileged due to their relative low-level major histocompatibility complex class I and II protein expression. Our placenta tissue derived MLASCs are potentially more immune privileged due to their fetal origin. In addition, because APPL cells have higher proliferative capability, they are expected to be more suitable for genetic manipulations to engineer the cells to have specific features to enhance their functions or to mitigate risk factors.

### Therapeutic Candidate Pipeline and Development Strategy

We are researching and developing multiple placental-derived allogeneic cellular therapeutic candidates for the treatment of indications across cancer, infectious and degenerative diseases. From a single source material, the placenta, we focus on four allogeneic cell types: CAR-T cells, unmodified NK cells, genetically modified NK cells, and MLASCs. We are also researching pEXO. Our product pipeline is represented in the diagram below:

Hematological Malignancies	Platform	Functionality	Indication	PRE-CLINICAL		CLINICAL	
				Discovery	IND-Enabling	Phase 1/2	Phase 2/3
CYNK-001	pNK	Unmodified	AML				
CYNK-301	pNK	IL15 + Marrow Homing + CAR	AML				
CYCART-19	pT	CD19 + TCR KO	NHL, MCL				
CYCART-201	pT	CD16 + TCR KO + mAb	NHL, MCL				
Solid Tumor	Platform	Functionality	Indication	Discovery	IND-Enabling	Phase 1/2	Phase 2/3
CYCART-201	pT	CD16 + TCR KO + mAb	HER2+ Tumors				
CYNK-302	pNK	CD16 + IL15 + CAR	NSCLC				
Autoimmune & Degenerative Disease	Platform	Functionality	Indication	Discovery	IND-Enabling	Phase 1/2	Phase 2/3
APPL-101	MLASC	TF KO	Crohn's Other potential indications				
pEXO-001	pEXO	Unmodified	Osteoarthritis				

### CYCART-19

Our lead therapeutic program based on our placental-derived CAR-T cell is CYCART-19, an allogeneic CAR-T cell targeting the CD19 receptor. We are granted certain rights related to the CD19 receptor construct and associated CARs utilized in CYCART-19 in the field of placenta-derived cells and/or cord blood-derived cells from Sorrento, a significant stockholder. For a description of the terms of the Sorrento license and our rights outside the field of placenta-derived cells and/or cord blood-derived cells, see the section entitled “*Licensing Agreements — Sorrento Therapeutics, Inc.*”.

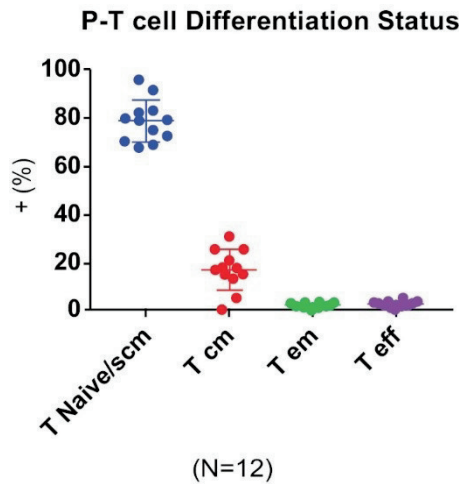
All currently FDA-approved CAR-T cell therapies, and an estimated approximately 75% of clinical assets in development, are autologous. Autologous therapies mean the peripheral blood-derived T-cell is the immune cell vehicle used to express a CAR, making the patient their own donor. Manufacturing these autologous CAR-T cell therapies is complex and costly, with a long vein-to-vein time that, can affect therapeutic outcomes. Moreover, multiple rounds of lymphocyte depleting therapies cause inconsistent apheresis cell recovery in relapsed or refractory patients. We believe that our placental-derived CAR-T cell, CYCART-19, is a scalable solution because it does not have apheresis capacity constraints is designed to be manufactured at high volume, and is delivered as an on-demand,

off-the-shelf, cryopreserved packaged product. Further, placental-derived cells contain an abundance of stem cell memory cells, which confers greater proliferative potential and increased persistence *in vivo*.

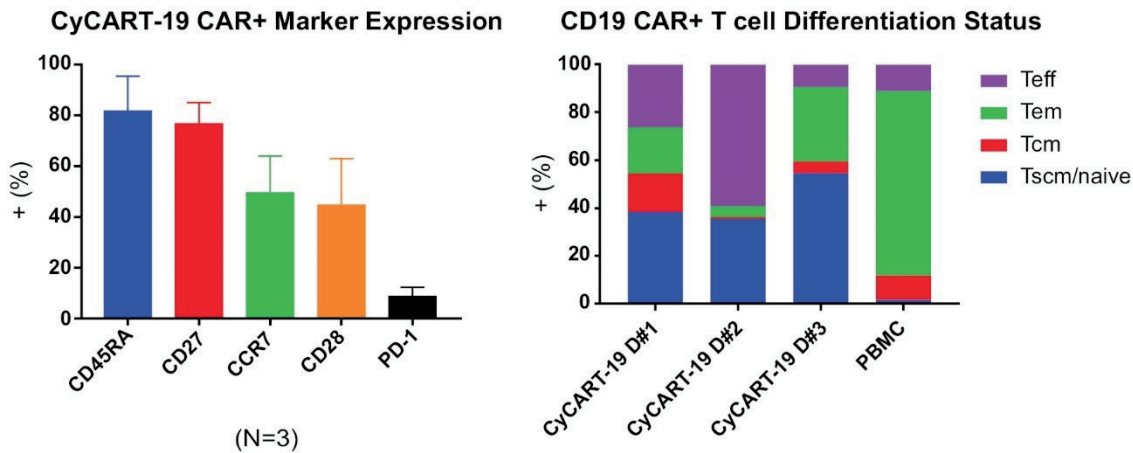
Preclinical Data

In preclinical studies, placental-derived T cells, which constitute the starting material for CYCART-19, were demonstrated to consist mostly of naïve/T stem cell memory cells, or T scm, with a small proportion of central memory T cells. Following genetic modification and proliferation/expansion in the laboratory, CYCART-19 cells expressed high levels of naïve/memory markers and low levels of the immune inhibitory molecule PD-1. Furthermore, CYCART-19 cells maintained a higher proportion of T scm, as compared to PBMC-derived CD19 CAR+ T cells, which signifies greater self-renewal, proliferative potential, lymphoid homing and increased ability to persist *in vivo*.

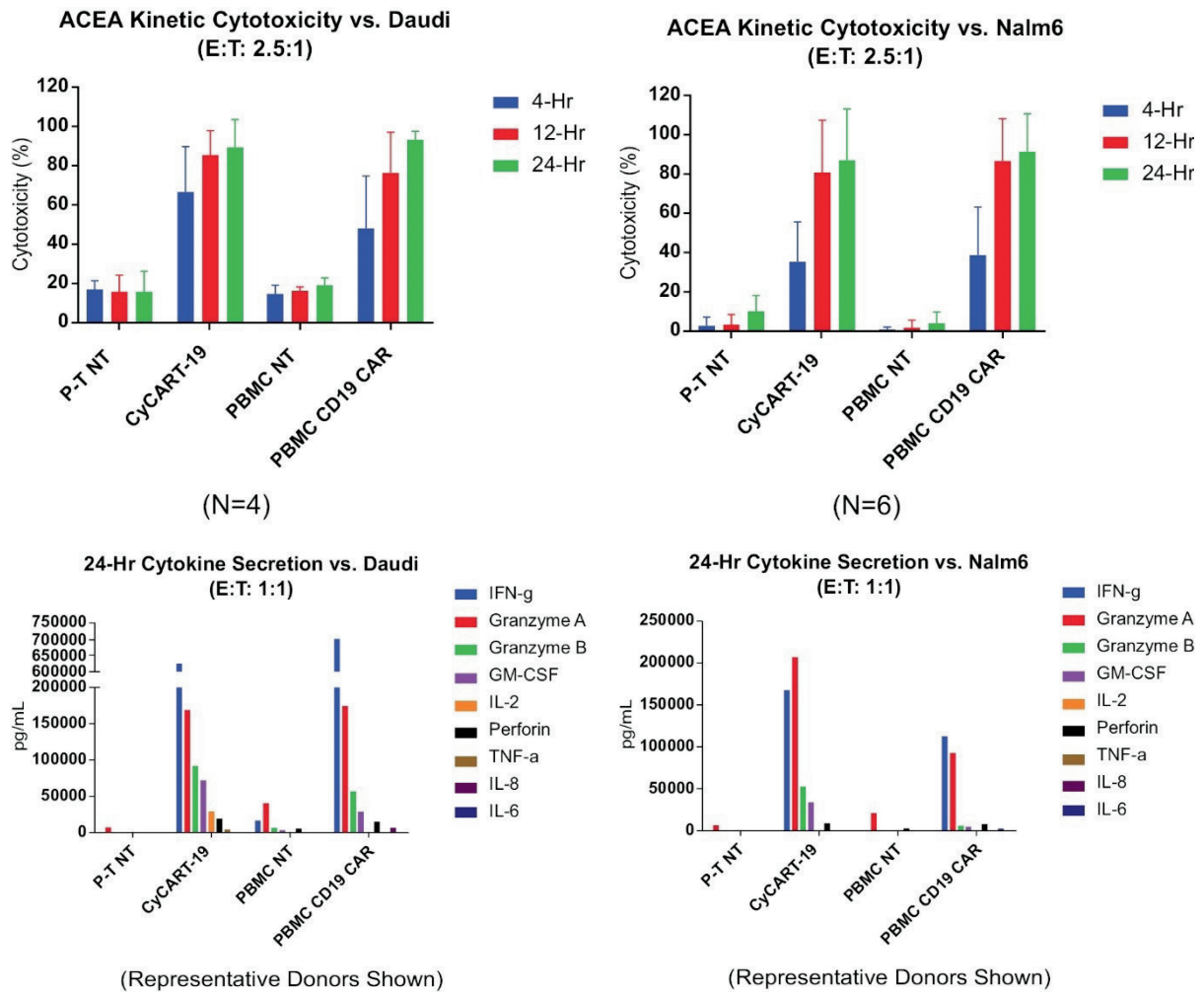
Day 0 P-T cells



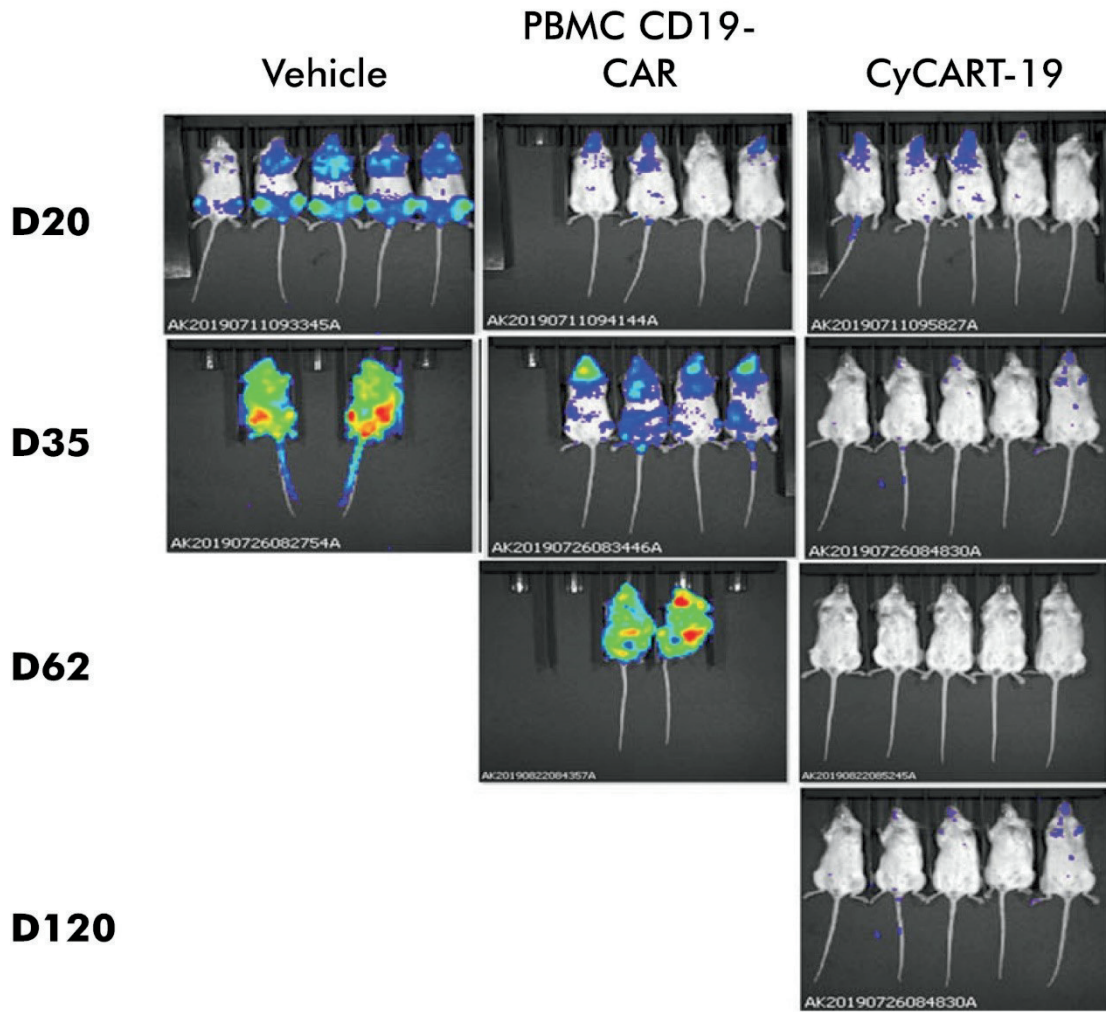
Day 15 CD19 CAR+T cells



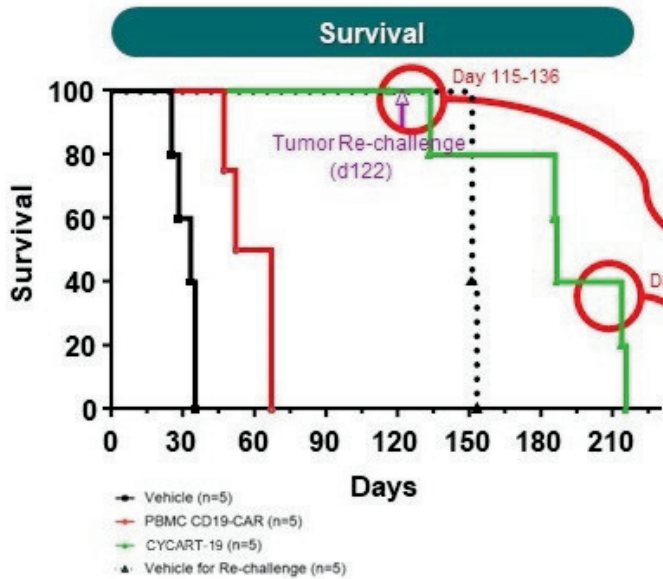
*In vitro*, CYCART-19 cells specifically lysed CD19+ targets Daudi (Burkitt's Lymphoma) and Nalm6 (Acute Lymphoblastic Leukemia) cell lines and secreted pro-inflammatory cytokines and effector proteins in response to these CD19+ targets.



# Bioluminescence Imaging

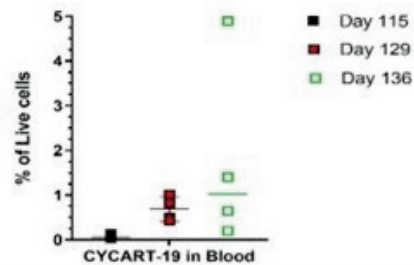




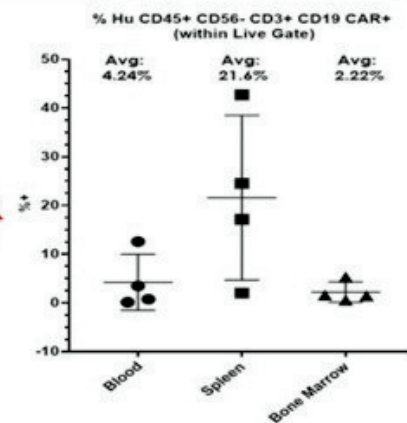


**CYCART-19: Capable of immediate re-expansion and exert tumor cell killing**

**CYCART-19 %**  
(Daudi rechallenge on Day 122)

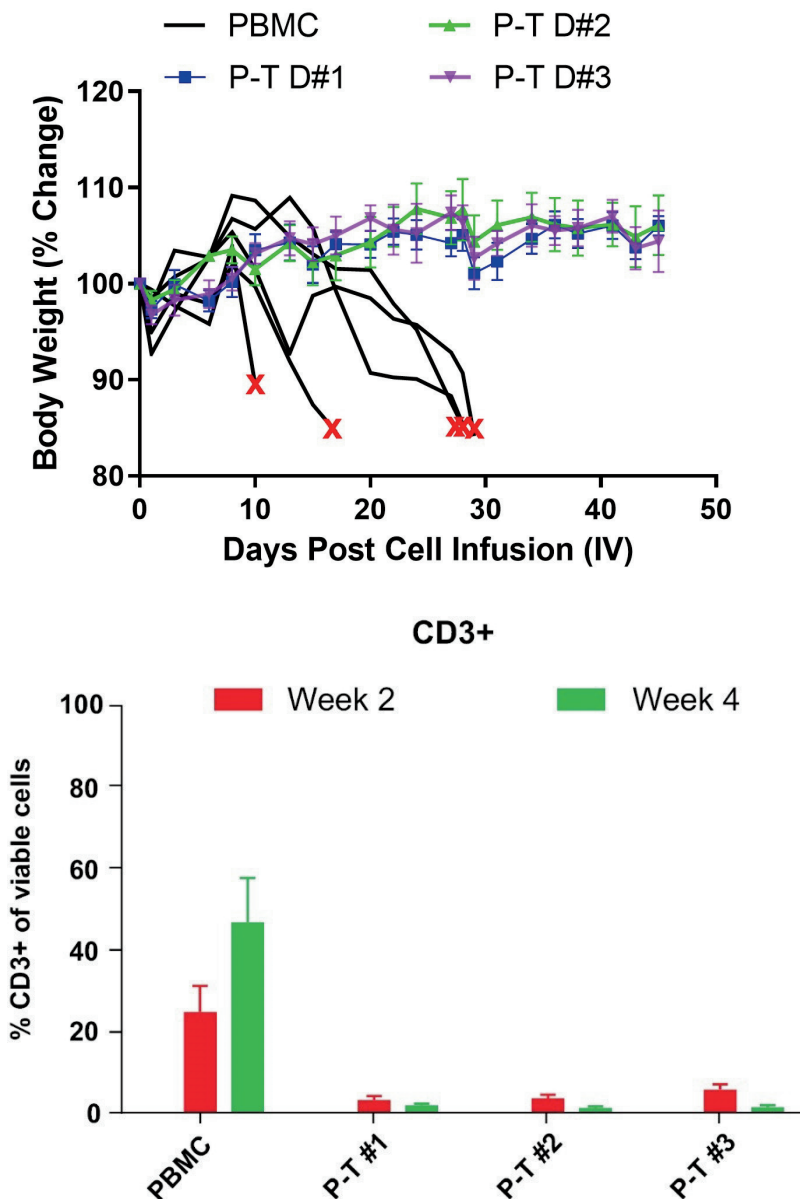


**CYCART-19: Durable Persistence**



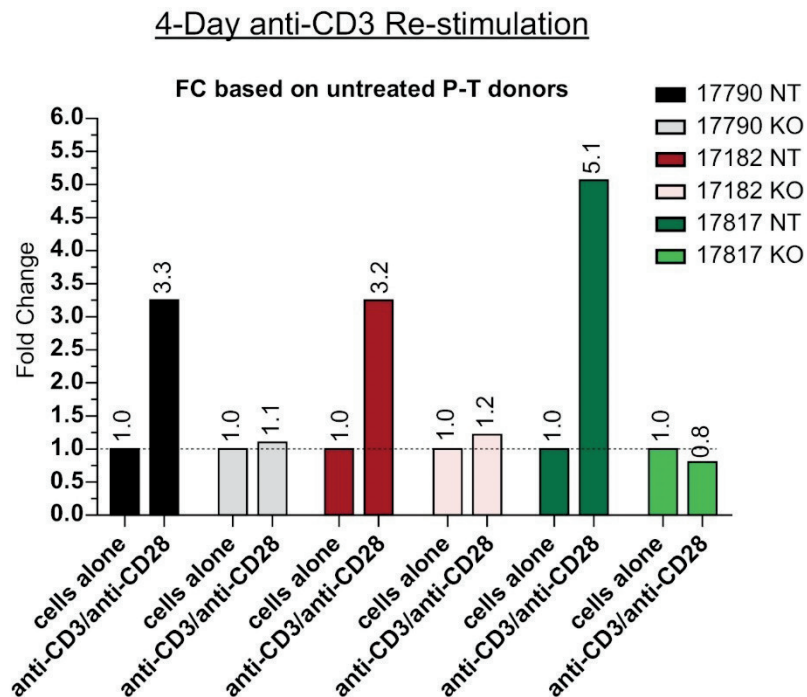
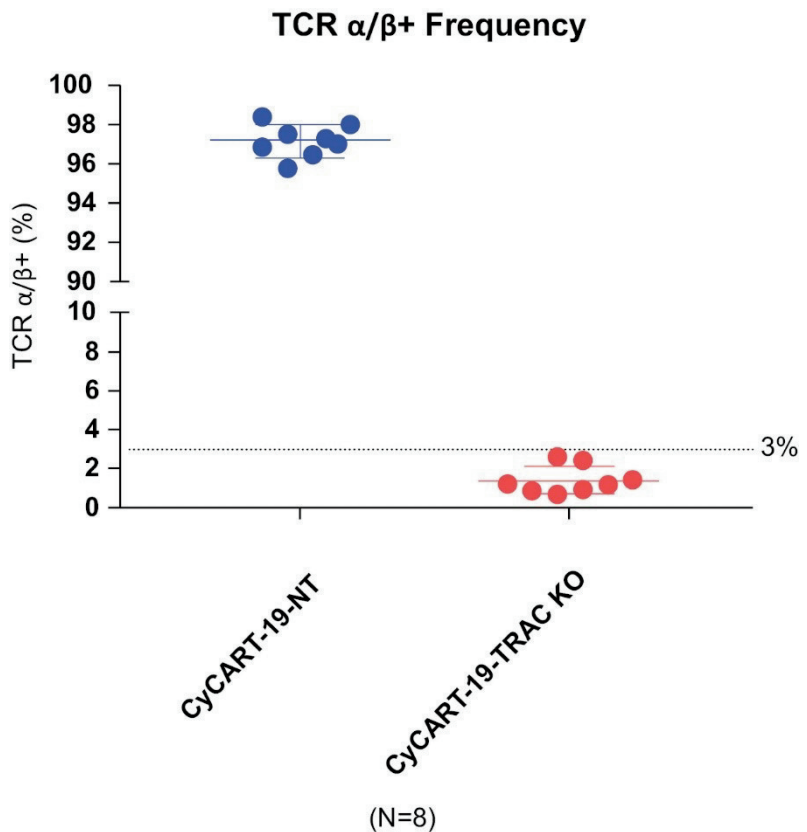
As shown in the preceding graphics, in mice models, CYCART-19 demonstrated superior anti-lymphoma activities and survival, indicating greater activity, persistence and prolonged immune attack upon tumor recharging as compared to adult-blood derived CD19 CAR-T cells. CYCART-19 eliminated tumor and resulted in 100% survival out to 120 days. CYCART-19 “memory” characteristics were demonstrated via extended survival out to 215 days upon tumor rechallenge on day 122, longer persistence, and greater lymphoid homing to the spleen at end of study to elicit prolonged antitumor activities. CYCART-19 cells used in animal studies were not T-cell receptor  $\alpha$  constant knockout, or TRAC KO, modified.

Placental-derived T cells are unique in that they can contribute to reduced alloreactivity responses and can be associated with lower incidences and severity of GvHD. As shown in the following graphic, expanded placental-derived T cells did not induce xenogeneic GvHD in *in vivo* mice models. This is evidenced by 100% survival, no weight loss, no increase in detection of any human CD3+ T cells in treated mice. PBMC-treated mice exhibited significant weight loss, death of all mice and increase of detection of human CD3+ T cells at day 28.



Despite the lack of evidence of GvHD with expanded placental-derived T cells, we do include a clustered regularly interspaced short palindromic repeats, or CRISPR, mediated T cell receptor alpha constant, or TRAC, knock-out, or KO, step in our process as a

further risk mitigation strategy to prevent GvHD. CYCART-19 transfected cells achieved 97-99% TRAC KO efficiency and demonstrated a loss of functional T cell receptor via lack of response (proliferation) to anti-CD3 restimulation.



*Planned Phase 1/2 Clinical Trial*

We plan to evaluate CYCART-19 for the treatment of B-cell malignancies (targeting the CD19 receptor) in a Phase 1/2 clinical trial.

The planned Phase 1 trial will evaluate safety and dosing and will include three dose cohorts (40, 120 and 360 x 10<sup>6</sup> transduced, viable CAR-T cells), in a 3x3 trial design, and will enroll up to 18 patients. The primary endpoint is to determine safety and maximum tolerated dose. Secondary endpoints are overall response rate, or ORR, (the sum of complete responses and partial responses, or CR+PR), duration of response, or DOR, progression-free survival, or PFS, and overall survival, or OS. We also intend to explore the persistence of CYCART-19.

The planned Phase 2 trial will evaluate efficacy of CYCART-19 and enroll 198 patients. The primary endpoint is to determine ORR (CR+PR). Secondary endpoints are safety, time to response, DOR, PFS and OS. We also intend to explore the persistence of CYCART-19.

In the first quarter of 2022, we submitted an IND to investigate CYCART-19 for treatment of B-cell malignancies and in late May 2022, received formal written communication from FDA requesting additional information before we can proceed with the planned Phase 1/2 clinical trial. We are in the process of working with the FDA in an effort to resolve its questions as promptly as possible. We expect to commence the trial, if the IND is cleared by the FDA, and sufficient funding is available, in second half of 2023. There is no assurance the IND will be allowed to proceed, will be allowed to proceed on the time frame contemplated or that the studies will be permitted to begin in the anticipated time frame.

### **CYCART-201**

CYCART-201 is genetically modified T-cell expressing CD16 with a TCR knockout. CYCART-201 is designed for use in combination with multiple potential mAbs with broad therapeutic potential. Our initial hematological development will be in NHL and our solid tumor development in HER2+ve tumors, both in combination with targeted mAbs.

### **CYNK-001**

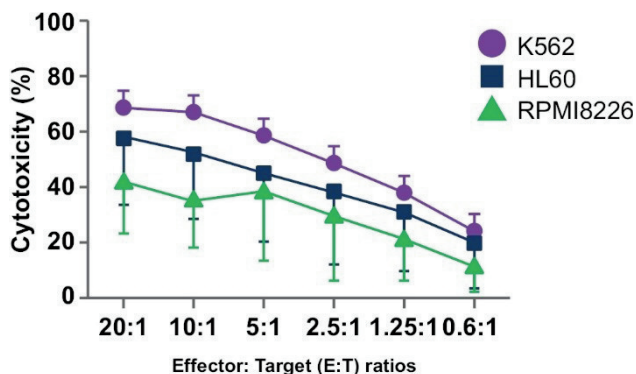
Our lead therapeutic program based on our placental-derived unmodified NK cell type is CYNK-001, an allogeneic unmodified NK cell being developed as a treatment for AML.

AML is the second most common type of leukemia in adults and children comprising about one-third of all adult leukemia cases. While most patients respond well to induction chemotherapy and achieve complete remission, two-thirds will relapse after frontline therapy. Patients who experience relapse following standard therapy (Relapsed/Refractory-R/R AML) and those that achieve a complete response but have residual measurable residual disease (MRD+ AML) have poor outcomes and remain an unmet medical need for new therapies. We are evaluating CYNK-001 administered to AML patients with either R/R AML or MRD+ AML. We seek to determine if CYNK-001 following the standard of care could further reduce AML burden in R/R AML and/or MRD+ AML potentially to below measurable residual disease (<0.1%) and if this translates to a clinical benefit that could lead to a registration trial.

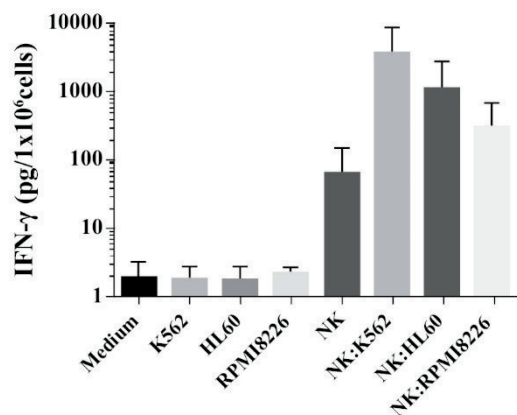
#### *Preclinical Data*

Preclinical studies of CYNK-001 showed evidence of significant killing against chronic myeloid leukemia, or ML, AML and MM, cell lines and primary AML samples. CYNK-001 activation released high concentration of IFN- $\gamma$ , a cytokine favoring Th1 anti-tumor responses, and CYNK-001 exerted up to 60% specific lysis against primary AML samples at an effector:target (E:T) ratio of 3:1.

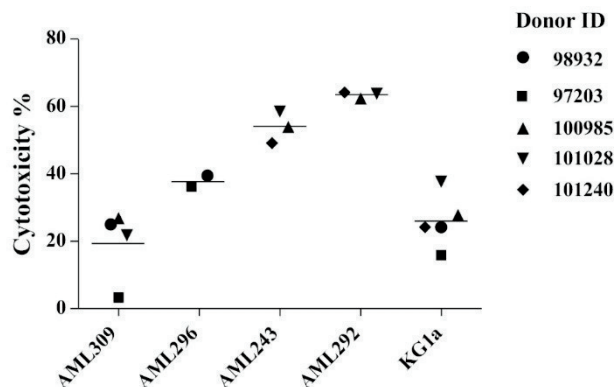
#### **CML, AML, MM *in vitro* killing**



## IFN- $\gamma$ Production



## Primary AML Killing



- Single or repeated dose of CYNK-001 significantly reduced bioluminescence imaging, or BLI, signal on D25, 28 and 35 compared with phosphate-buffered saline control
- Repeated dose significantly reduced BLI signal on D25, 28 and 35 compared with CYNK-001 single dose

### Phase 1 Trial

We have completed a Phase 1 dose escalation trial that enrolled 11 relapsed/refractory AML patients, treating 10 with a single dose of PNK-007, a prior formulation of CYNK-001 that was not cryopreserved. The cell therapy was generally well tolerated, with no dose-limiting toxicities, no GvHD, and no detectable HLA allo-antibody. Eight of 10 patients were efficacy evaluable (two were not due to inadequate bone marrow for evaluation) and two of four of these patients treated with the highest dose (approximately 700 million NK cells) had evidence of a transient biologic effect.

We are currently enrolling a follow-up Phase 1 trial for CYNK-001, the cryopreserved NK cell formulation equivalent of PNK-007, in patients with relapsed/refractory AML and patients in hematologic remission with minimal residual disease, or MRD. As part of the CYNK-001 Phase 1 trial, we assessed dosing of lymphodepletion to maintain serum IL-15 levels above baseline and T regulatory cells at low levels for up to 28 days, or Window of dosing opportunity, to potentially enhance potency and persistence of NK cells. In total, 16 patients have been enrolled and treated with R/R AML and ten patients with MRD+ AML and there have been no dose limiting toxicities observed at any dose level to date including total dose levels of 1.8, 3.6 and 5.4 billion CYNK-001 cells. There has been the achievement of MRD negative status at highest CYNK-001 cell dose level with documented persistence of CYNK-001 cells in bone marrow and peripheral blood at 28 days post Day 0 Infusion. To potentially further enhance CYNK-001 potency and persistence, the expansion arms in MRD and R/R AML use an augmented lymphodepletion protocol of Cytosan 3600 mg divided over four days (versus prior 900 mg divided over three days) and fludarabine 120 mg divided over four days (versus prior 75 mg divided over three days) to increase post lymphodepletion IL-15 levels. Management will evaluate a potential path for the remainder of the AML study after review of the trial to date results including the 6B cohort. In December 2021, we received fast track designation from the FDA for CYNK-001 for the treatment of AML.

In the fourth quarter of 2021, we initiated a Phase 1 dose escalation trial in recurrent GBM of intravenous and intra-tumoral bed CYNK-001 cells to evaluate dose, NK cell homing and persistence, safety, and biologic effect. We received fast track designation from the FDA for CYNK-001 for the treatment of recurrent GBM in March 2021 and received orphan drug designation from the FDA for CYNK-001 for the treatment of GBM in April 2021. Due to a need to prioritize corporate resources, in January 2023, we announced our intention to cease recruitment in the GBM trial.

### CYNK-301

Building on our experience in AML, CYNK-301 is our next generation CAR-NK that has the potential to overcome some of the challenges faced by NK therapies in treating rAML including minimizing the burden of lymphodepletion, while optimizing proliferation, persistence and efficacy. CYNK-301 incorporates membrane bound IL15 to enhance NK cell activation, proliferation and persistence, with additionally, marrow homing and a targeted CAR to further enhance efficacy.

## **CYNK-302**

CYNK-302 is a CAR-NK being developed in solid tumors with an initial focus on NSCLC, an area of continued high unmet need. CYNK-302 is a next-generation construct building on our learning from CYNK-101 in HER2+ve gastric cancer. It is an optimized construct which is genetically modified to express CD16 as a universal engager and is further enhanced by incorporating membrane bound IL15 to support proliferation and persistence and an undisclosed targeted CAR to further enhance efficacy.

## **APPL-001**

The current lead therapeutic candidate from our placental-derived MLASC type is APPL-001, a genetically modified placental-derived MLASC. We are initially evaluating APPL-001 for the treatment of Crohn's disease. In clinical studies of unmodified MLASCs, over 50 patients were dosed with MLASCs for the treatment of Crohn's disease. Clinical response rates were significantly higher in treatment groups compared with the placebo group.

### *Phase 1/2a Trial Design*

The planned Phase 1/2a trial will evaluate APPL-001 in patients with moderate to severe Crohn's disease who are refractory to corticosteroids. The primary objective is to assess the safety and tolerability and to establish recommended Phase 2 dose. The primary objective in the planned Phase 2a part of the trial will be evaluation of clinical activity by measuring clinical remission and clinical response in subjects with moderate to severe Crohn's disease. Secondary objectives are to assess disease modifying measures such as endoscopic measurements and quality of life assessments. The planned primary endpoint is clinical remission/response at six weeks and after one year. Planned secondary endpoints include evaluation of mucosal healing, and patient-reported outcome of quality of life as measured by Inflammatory Bowel Disease Questionnaire.

## **pEXO-001**

pExo-001 is a human postpartum placenta derived exosome product which consists of cytokines, chemokines, and growth factors that have been reported to have regenerative and immuno-regulatory activities. The initial development of pExo-001 will be in osteoarthritis.

## **Future Pipeline Opportunities**

We plan to utilize our Celularity IMPACT platform to pursue additional targets of interest. These include the additional indications for the four allogeneic cell types currently in the pipeline as well as other targets that might be validated in the future. Our placental-derived T cell platform has potential to target other receptors.

In addition, we regularly survey the scientific and industry landscape for opportunities to license, partner or acquire technologies that may help us advance current or new cell therapies for the benefit of patients.

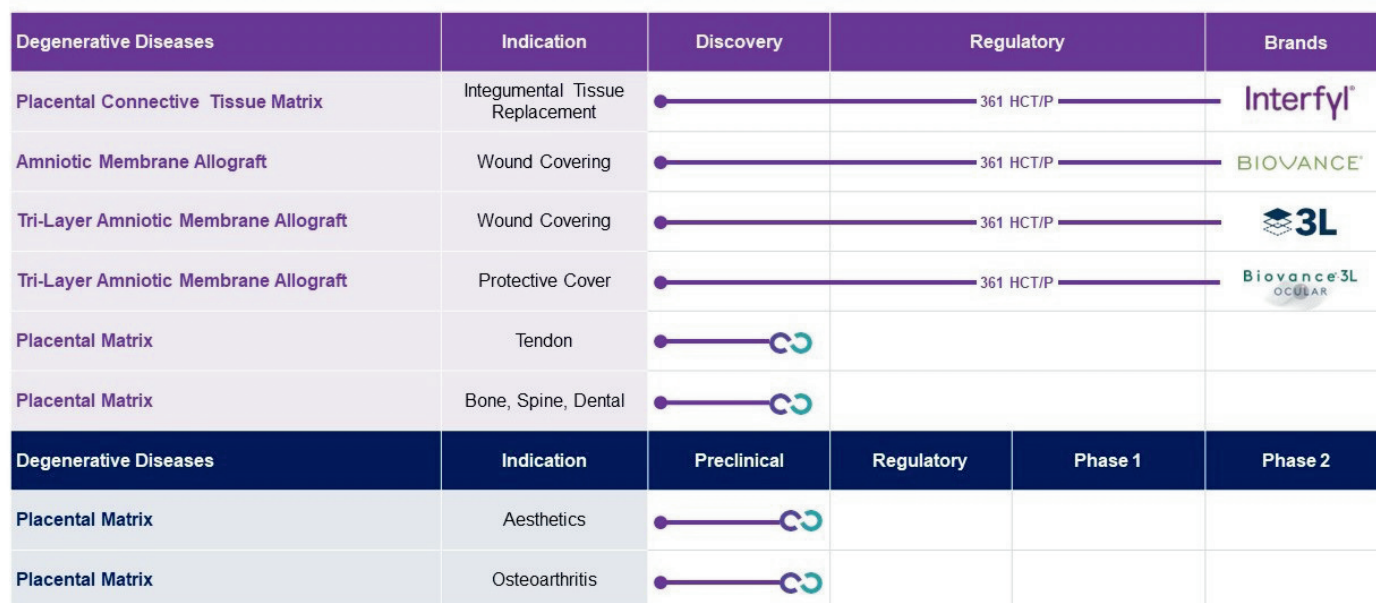
Our ability to prosecute future opportunities including those with scientific and potential commercial merit may be influenced by our ability to raise sufficient capital to pursue those opportunities or to find commercial partners that are willing and able to fund portions of their development. Co-developed or partnered programs may have longer term economics that are less favorable than internally funded programs, but those programs also may have higher odds of success with a well capitalized development partner with specific expertise in the disease state under investigation.

## **Commercial Businesses**

We are continuing to invest in new biomaterials programs to expand our pipeline of placentally derived biomaterial products. We are currently developing a tendon wrap indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. We are also developing a bone void filler product for use in orthopedic surgical markets. We have



preliminary data from a knee osteoarthritis animal model that placentally derived extracellular matrix may decrease joint pain and promote chondrogenesis in damaged cartilage. Our product pipeline is represented in the diagram below:



## Degenerative Diseases

We report our operating results including a segment we call Degenerative Disease. The National Cancer Institute defines “degenerative disease” as a disease in which the function or structure of the affected tissues or organs changes for the worse over time. Our degenerative disease business today is comprised primarily of the sale of our Biovance and Interfyl products, directly or through our distribution network. Biovance is decellularized, dehydrated human amniotic membrane derived from the placenta of a healthy, full-term pregnancy. It is an intact, natural extracellular matrix that provides a foundation for the wound regeneration process and acts as a scaffold for restoration of functional tissue. Interfyl is human connective tissue matrix derived from the placenta of a healthy, full-term pregnancy. It is used by a variety of medical specialists to fill soft tissue deficits resulting from wounds, trauma, or surgery. We are investigating additional biomaterial products for use in treating degenerative diseases as well as applications in degenerative diseases for our proprietary cell therapies and possible combination therapies that use of a biomaterial or biomaterials in combination with a cell therapy. Biovance and Interfyl were developed at Anthrogenesis prior to the Celgene acquisition and sold to HLI by Celgene, and then acquired by us from HLI in May 2017, subject to marketing and distribution rights licensed by HLI to a third party, which rights were acquired by us in May 2018, along with the MIST and UltraMIST Therapy Systems. In August 2020, we entered into a five-year licensing arrangement with Sanuwave Health Inc., or Sanuwave that included: (i) an exclusive Biovance license for distribution and commercialization in the wound care market and (ii) a non-exclusive license for the distribution and commercialization of Interfyl in the wound care market worldwide, except certain Asian jurisdictions, pursuant to which we were to receive royalties based on minimum sales thresholds. The license agreement with Sanuwave was terminated during the third quarter of 2021 due to an uncured material breach.

We have focused our marketing and sales strategy within the Degenerative Disease segment on developing strong distribution partners for our products rather than building out our own direct sales force. On May 7, 2021, we entered into a six-year supply and distribution agreement with Arthrex, Inc., that includes: (i) an exclusive Biovance, Interfyl, and Centaflex license for distribution and commercialization within the United States in the field of orthopedic surgery; and (ii) an exclusive license to commercialize and distribute Interfyl and Centaflex within the United States in the field of acute and chronic non-healing wound care. On September 1, 2021, we entered into a three-year supply and distribution agreement with Evolution Biologyx, LLC that includes an exclusive license to commercialize and distribute Interfyl in the United States within any medical specialty where Interfyl is administered in an in-office or in-patient setting and is reimbursed through Medicare Part B or any successor, equivalent or similar category established by the U.S. Department of Health and Human Services Center for Medicare Services or other government authority, except in the medical specialty of orthopedic surgery excluding trauma or spine applications in the medical specialty of orthopedic or neurologic surgery.

During January 2023, we announced two new distribution agreements related to our expansion outside of the United States into the Middle East and North Africa. We entered into an exclusive territory distribution agreement with CH Trading Group LLC, or CH Trading Group, an international import, export and trading company. CH Trading Group will act as the exclusive territories distributor of our Halal-Certified products within more than 100 countries in the Middle East and North Africa. Further, we announced an exclusive

distribution agreement with the Tamer Group, or Tamer, a Middle East healthcare distribution company, for the distribution of our branded biomaterial products in Saudi Arabia. During March 2023, we also announced we executed an exclusive distribution agreement with Abu Dhabi Ports Company, or AD Ports, a leading global facilitator of trade, logistics and industry based in Abu Dhabi, United Arab Emirates, for the distribution of our biomaterial products in United Arab Emirates, Qatar, Bahrain, Oman, Kuwait and Egypt.

We continue to invest in creating new or differentiated products for the Degenerative Disease segment to supplement sales of our mature commercial products, Biovance and Interfyl. We have created Biovance 3L, a trilayer human amniotic membrane product focused on the ocular and surgical markets. Biovance 3L is available in both sheet and disk form depending upon the application. We have also created CentaFlex, a decellularized human placental matrix derived from the umbilical cord. CentaFlex can be used as a surgical covering, wrap or barrier to protect and support the repair of damaged tissue. We have other products based on human placental tissue under development that may follow a variety of regulatory pathways to potentially achieve commercial readiness.

### ***Biobanking***

We provide a fee-based biobanking service to expectant parents who contract with the company to collect, process, cryogenically preserve and store certain biomaterial, including umbilical cord blood and placenta derived cells and tissue. We receive a one-time fee for the collection, processing and cryogenic preservation of the biomaterials, and a storage fee to maintain the biomaterials in our biobank payable annually generally over a period of 18 to 25 years. We acquired our biobanking business in May 2017 from HLI, which HLI operated as LifebankUSA, along with the degenerative disease products Biovance and Interfyl, and in October 2018, we acquired CariCord Inc., or CariCord, a family cord blood bank.

### **Manufacturing**

We have a 147,215 square foot purpose-built facility located in Florham Park, New Jersey, which includes a cGMP-ready manufacturing center, along with dedicated research and office spaces and space for shared services. Our facility includes nine Grade C/ISO-7 and six Grade D/ISO-8 manufacturing suites designed for commercial production of cellular therapies and advanced biomaterials. We intend to manufacture all finished product in-house at our manufacturing facility in Florham Park, New Jersey. We have invested resources to optimize our manufacturing process, including the development of improved analytical methods. We plan to continue to invest in process science, product characterization and manufacturing to improve our production and supply chain capabilities over time. We have also used CMOs, as needed, on a non-exclusive basis, and may use CMOs in the future, for certain of our therapeutic candidates. For example, we used a CMO for the clinical manufacture and supply of CYNK-001 through 2022 which we internalized the manufacture for and anticipate that all finished product will be manufactured in-house going forward. All other finished products are manufactured in-house. Notwithstanding, we will engage CMOs as necessary to ensure continuous supply of clinical and commercial grade product based on demands.

Our cellular therapeutic candidates are designed and manufactured via a platform comprised of defined unit operations and technologies. The process is gradually developed from small to larger scales, incorporating compliant procedures to create cGMP conditions. Notwithstanding this platform-based model, each therapeutic is unique and for each new therapeutic candidate, a developmental phase is necessary to individually customize each engineering step and to create a robust procedure that can later be implemented in a cGMP environment to ensure the production of clinical batches. This work is performed in a research and development environment to evaluate and assess variability in each step of the process in order to define the most reliable production conditions.

We plan to leverage our core expertise in cellular therapeutic development and manufacturing to generate revenues by providing contract manufacturing and development services to third parties. The initial focus of this new service offering will be to assist development stage cell therapy companies with the development and manufacturing of their therapeutic candidates for clinical trials. We believe that we will be able to provide a flexible and cost effective alternative to the larger contract manufacturing organizations currently serving this market.

### **Licensing Agreements**

We enter into license agreements in the ordinary course of our business. We have in-licensed certain technology from Sorrento that is necessary to research and develop our CYCART-19 program. Because of the broad potential applicability of our placental-derived cellular therapeutic candidates, we may also out license our technology to third parties for development for other indications that we do not intend to pursue or for certain territories. For example, in June 2017, we entered into a license agreement with Lung Biotechnology PBC. Under that license agreement, which was terminated in March 2021, we granted Lung Biotechnology PBC an exclusive license to placental-derived stem cells in the field of pulmonary diseases and organ transplantation. We have also licensed rights to distribute our degenerative disease products, Biovance and Interfyl, to Sanuwave for a five-year period in connection with the August 2020 sale of other non-core assets, however we terminated this license in the third quarter of 2021.

Further, as part of the acquisition of Anthrogenesis from Celgene, we granted Celgene a worldwide, royalty-free, fully paid up, non-exclusive license, to use certain intellectual property for both research and commercial purposes, and granted Celgene the CVRs,



which provide us the right to future milestone and royalty payments in certain circumstances. See the section entitled “— *Our Team and Corporate History — Celgene Corporation*” for a description of the ongoing relationship between us and Celgene, including the out license agreement and the CVRs.

### ***Sorrento Therapeutics, Inc.***

In September 2020, we entered into a license and transfer agreement with Sorrento to obtain rights to Sorrento’s proprietary anti-CD19 CAR-T construct and associated CARs for use in placenta-derived or cord blood-derived cells. Sorrento is a significant stockholder of ours. We are using Sorrento’s technology to genetically modify our placental-derived T-cell to create the CAR T-cell with a CD19 receptor that is our CYCART-19 therapeutic candidate.

Pursuant to the Sorrento Agreement, we obtained a worldwide license, with the right to grant sublicenses with Sorrento’s consent, under certain of Sorrento’s intellectual property rights, including patent rights that would be infringed by the use of certain CD19 CAR constructs, to research, develop, use, reproduce, modify, and create derivative works in the field of placenta-derived cells and/or cord blood-derived cells for the treatment of any disease or disorder, and to make, have made, use, sell, offer for sale, import, export, and distribute products for use in connection with our research, development, commercialization and exploitation of products combining Sorrento’s proprietary anti-CD19 CAR-T construct and associated CARs with placenta-derived or cord blood-derived cells. The foregoing license is exclusive with respect to a certain U.S. provisional patent application and non-exclusive with respect to all other licensed intellectual property rights of Sorrento.

Sorrento reserves the right to make, have made, use, sell, offer for sale, import, export, and otherwise research, develop, commercialize and exploit CD19 CAR-T licensed products for use outside the field of placenta-derived cells and/or cord blood-derived cells for the treatment of any disease or disorder and any other products or services that are not CD19 CAR-T licensed products that use or incorporate any CD19 CAR-T constructs or associated CARs.

Under the Sorrento Agreement, we have sole responsibility for the development and commercialization of licensed products, subject to certain reserved rights of Sorrento with respect to CD19 CAR-T products. We are currently negotiating a supply agreement with Sorrento to obtain the continued supply of CAR constructs and licensed products under the Sorrento Agreement. Additionally, we are obligated to use commercially reasonable efforts to develop and commercialize licensed products.

Pursuant to the Sorrento Agreement, we have agreed to assign all right, title and interest in any improvements generated by us to Sorrento’s background intellectual property. Additionally, we have granted Sorrento a non-exclusive, sublicensable, fully paid-up, royalty free, worldwide license under any new inventions that relate to or cover CD19 CAR-T constructs generated by us under the Sorrento Agreement for use in connection with Sorrento’s reserved rights under CD19 CAR-T licensed products and constructs (as described above). Sorrento has the primary right to control the prosecution and maintenance of patents and patent applications arising out of or relating to the Sorrento Agreement, including any patents or patent applications covering the licensed products, while we have the secondary right to pick up prosecution of any such patents and patent applications abandoned by Sorrento.

Under the Sorrento Agreement, we are obligated to pay Sorrento a low teens double digit percentage of non-royalty sublicensing income payments received by us in connection with a grant of any sublicense for CD19 CAR-T licensed products. Additionally, we are obligated to pay Sorrento a low single-digit royalty on net sales of CD19 CAR-T licensed products in perpetuity. We will also be obligated to pay Sorrento for the supply of the CAR constructs and licensed products pursuant to the supply agreement, once finalized, which we expect to be based on the cost plus a percentage, with no guaranteed minimums. As of December 31, 2022, we have not paid Sorrento any amounts under the Sorrento Agreement but have made payments for supply of products while continuing to negotiate the supply agreement.

Either party may terminate the Sorrento Agreement upon an uncured material breach of the Sorrento Agreement by the other party. Additionally, after the first anniversary of the effective date of the Sorrento Agreement, we have the right to terminate the Sorrento Agreement at any time upon specified written notice to Sorrento. On February 13, 2023, Sorrento announced that it commenced voluntary proceedings under Chapter 11 of the U.S. Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of Texas. At this time, we cannot predict what impact the bankruptcy will have on Sorrento’s continued ability to perform under the license agreement.

### **Intellectual Property**

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for the technologies supporting our Celularity IMPACT platform, and our lead cellular therapeutic candidates, CYCART-19, CYNK-001, CYNK-101, APPL-001, PDA-002 and future therapeutic candidates, as well as novel discoveries, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among

other methods, filing or in-licensing U.S. and foreign patents and applications related to our technology, inventions, and improvements that are important to the development and implementation of our business.

We also rely on trademarks, trade secrets, know-how, continuing technological innovation, confidentiality agreements, and invention assignment agreements to develop and maintain our proprietary position. The confidentiality agreements are designed to protect our proprietary information and the invention assignment agreements are designed to grant us ownership of technologies that are developed for us by our employees, consultants, or other third parties. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. In addition, our trade secrets may otherwise become known or independently discovered by competitors.

With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial therapeutics and methods of using and manufacturing the same.

We are actively building our intellectual property portfolio around our Celularity IMPACT platform, our four allogeneic cell types and our therapeutic candidates based on our own intellectual property as well as licensed intellectual property. We are the owner of, co-owner of, or the licensee of over 1,500 patents and patent applications in the United States and worldwide protecting our Celularity IMPACT platform, our processes, technologies and current key cell therapy programs.

Our patent portfolio includes patents and patent applications directed toward our five allogeneic placental-derived cell and extracellular vesicle types: CAR-T cells, unmodified NK cells, genetically modified NK cells, MLASCs and exosomes as follows:

- We have six utility patent families in the CAR-T technology area supporting our CYCART-19 and CYCART-201 therapeutic candidates comprising three patent families owned by us to support both CYCART-19 and CYCART-201 and three patent families licensed from Sorrento to support CYCART-19. These patent applications include licensed CAR-T patent families and owned placental-derived CAR-T patent families directed toward early CAR receptor technology, CAR receptor method and composition, anti-CD19 CAR receptor and product characterization. Patents issuing from these families have expected expiry dates ranging from 2039 to 2042 and include pending patent applications in the United States and under the PCT, Australia, Brazil, Canada, China, Eurasian Patent Organization, European Patent Convention, Hong Kong, India, Japan, Korea, Mexico, New Zealand, Philippines, Singapore, and South Africa.
- We have approximately 15 utility patent families owned by us in the NK technology area supporting our CYNK-001, CYNK-301 and CYNK-302 therapeutic candidates that include patents and patent applications covering process, treatment of indications, and product characterization. Patents issuing from these families have expected expiry dates ranging from 2028 to 2041 and include patents issued and pending patent applications in the United States and under the PCT, Australia, Brazil, Canada, China, Colombia, Eurasian Patent Office, European Patent Office, Hong Kong, Israel, India, Indonesia, Japan, Republic of Korea, Mexico, Malaysia, New Zealand, Russian Federation, Singapore, Taiwan R.O.C., Ukraine, Vietnam, and South Africa.
- We have approximately 25 utility patent families owned by us in the MLASC technology area supporting our APPL-001 therapeutic candidate and former legacy MLASC candidates that include patents covering product characterization and method of production, as well as product description and indications. Patents issuing from these families have expected expiry dates ranging from 2023 to 2040 and include patents issued and pending patent applications in the United States and under the PCT, Argentina, Australia, Brazil, Canada, China, Colombia, Eurasian Patent Office, European Patent Office, Hong Kong, Israel, India, Indonesia, Japan, Republic of Korea, Mexico, Malaysia, New Zealand, Peru, Russian Federation, Singapore, Taiwan R.O.C., Ukraine, Venezuela, Vietnam, and South Africa. Although patent families in this technology area began to expire in 2021, we have numerous patent families in this technology area directed to improvements in the cells and methods/indications for their use, which include recently filed applications directed towards APPL-001, a second generation, genetically modified MLASC therapeutic candidate. These applications have projected expiration dates to 2041 and are expected to replace the early-expiring applications. Accordingly, we do not expect that the expiry of the early-filed MLASC patents will have a material effect on our business.
- We have four utility patent families in the exosome technology area supporting our placental exosome candidates. These patent applications include product characterization focused on identifying and protecting the key molecular markers that define these unique exosome populations and establish protection for their anti-inflammatory and immunomodulatory properties as well as for their use in the treatment of specific indications such as osteoarthritis. Patents issuing from these families have expected expiry dates ranging from 2035 to 2043 and include issued patents and pending patent applications in the United States and under the PCT, Australia, Canada, China, Eurasian Patent Organization, European Patent Convention, Hong Kong, India, Japan, Korea, Mexico, New Zealand, Philippines, Singapore, and South Africa.

More generally, our patent portfolio and filing strategy is designed to provide multiple layers of protection by pursuing claims directed toward composition of matter, methods of making, and methods of use, amongst others. We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking patent protection intended to cover our technology and related technologies and uses thereof.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the United States, patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent or 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 a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to, among other things, compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension is calculated based on the length of time we take for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be restored. Moreover, a patent can only be restored once, and thus, if a single patent is applicable to multiple products, we can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

## Competition

Our products will compete with novel therapies developed by biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions, in addition to existing standard of care treatments.

Due to the promising therapeutic effect of cell therapies in clinical trials, we anticipate increasing competition from existing and new companies developing these therapies, as well as in the development of allogeneic cell therapies.

Potential cell therapy and biomaterials competitors include:

- *CYCART-19 and CYCART-201; allogeneic CAR-T cell therapies:* Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Collectis S.A., Fate Therapeutics Inc. and Precision Biosciences, Inc.
- *CYNK-001, CYNK-301 and CYNK-302; allogeneic NK cell therapies:* Fate Therapeutics Inc., Sanofi S.A. (acquired Kiadis Pharma N.V.), Century Therapeutics, Inc. and Nkarta, Inc.
- *APPL-001; allogeneic MLASC therapies:* Mesoblast Limited.
- *pEXO-001; exosomes:* Aegle Therapeutics Corporation, Capricor Therapeutics, Inc., Evox Therapeutics Ltd., and Organiceell Regenerative Medicine, Inc.
- *Cell therapy competition:* Allogene Therapeutics, Inc., Atara Biotherapeutics, Inc., Adaptimmune Therapeutics PLC, Celyad S.A., CRISPR Therapeutics AG, Intellia Therapeutics, Inc., Gilead Sciences, Inc., Poseida Therapeutics, Inc., Precision Biosciences, Inc. and Sangamo Therapeutics, Inc.
- *Biomaterials competition:* Mimedx Group, Inc., and Organogenesis Holdings Inc.

Competition will also arise from non-cell-based therapies pursued by small-cap biotechnology and large-cap pharmaceutical companies including Amgen Inc., AstraZeneca plc, Bristol Myers Squibb Company, Incyte Corporation, Merck & Co., Inc. and F. Hoffmann-La Roche AG.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize therapeutics that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than cellular therapeutics that we may develop. Our competitors also may obtain FDA or other regulatory approval for their therapies more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make development efforts more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience.

These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, as well as for technologies complementary to, or necessary for, our programs.

## Government Regulation and Product Approval

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our cell therapeutics will be regulated as biologics. With this classification, commercial production of our cellular therapeutics will need to occur in registered facilities in compliance with cGMP for biologics. The FDA categorizes human cell or tissue-based products as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a biologics license application, or BLA, for marketing authorization. Our cellular therapeutic candidates are considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them.

Government authorities in the United States (at the federal, state and local level) 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 biopharmaceutical products such as those we are developing. Our therapeutic candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agencies before they may be legally marketed in foreign countries. 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 biological products under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or PHSA, and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's 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 our operation and business. The process required by the FDA before a biological product 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 IND, 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 site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices 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 a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product 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 GTPs, for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including our cellular therapeutic candidates, in humans, the therapeutic candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of 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 GLPs. 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. The IND automatically 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 biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials 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.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the National Institutes of Health, or NIH, Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators, generally 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 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. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the good clinical practice, or GCP, requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent 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 that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if we determine that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

- *Phase 1.* The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, 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. During all phases of clinical development, regulatory agencies require extensive monitoring

and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Human cellular therapy products are a new 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 trial period, the number of patients the FDA will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of cellular therapy 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 biological product 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 product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

### ***U.S. Review and Approval Processes***

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the 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 BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. 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 BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also 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 BLA. The FDA reviews the 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 FDA may refer applications for novel biological products or biological 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 decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and 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. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the therapeutic unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the therapeutic within required specifications. For cellular therapies, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, 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, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. Additionally, before approving a 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, GTP 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 November 2017, the FDA released a guidance document entitled “Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue — Based Products: Minimal Manipulation and Homologous Use — Guidance for Industry and Food and Drug Administration Staff”, which it revised and reissued in July 2020, or the Guidance. The document confirmed the FDA’s stance that sheet forms of amniotic tissue are appropriately regulated as solely Section 361 HCT/Ps when manufactured in accordance with 21 CFR Part 1271 and intended for use as a barrier or covering. The primary intent of the GTP requirements is to ensure that cell and tissue-based therapeutics are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Although FDA had indicated in its Guidance that the agency would exercise enforcement discretion under limited conditions with respect to the IND application and pre-market approval requirements for certain HCT/Ps, this period of enforcement discretion ended May 31, 2021.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a therapeutic receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the therapeutic. Further, the FDA may require that certain contraindications, warnings or precautions be included in the labeling. The FDA may impose restrictions and conditions on distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product’s safety and effectiveness, and testing and surveillance programs to monitor the safety of approved therapeutics that have been commercialized.

In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a 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. Unless otherwise required by regulation, PREA does not apply to any product for an indication for which orphan designation has been granted. However, if only one indication for a therapeutic has orphan designation, a pediatric assessment may still be required for any applications to market that same therapeutic for the non-orphan indication(s).

### ***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic 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 a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a therapeutic that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the therapeutic is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full 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 therapeutic with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from

approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States 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 April 2021, the FDA granted orphan drug designation to our non-genetically modified cryopreserved human placental hematopoietic stem cell-derived NK cell therapy, CYNK-001, for the treatment of patients with malignant gliomas.

### ***Expedited Development and Review Programs***

The FDA has programs intended to facilitate and expedite the development and review of new drugs to address unmet medical needs in the treatment of a serious or life-threatening condition. These programs include fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. Specifically, new therapeutics are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the therapeutic and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any therapeutic submitted to the FDA for approval, including a therapeutic with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A therapeutic is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed therapeutics. The FDA will attempt to direct additional resources to the evaluation of an application for a new therapeutic designated for priority review in an effort to facilitate the review. Additionally, a therapeutic may be eligible for accelerated approval. Therapeutics studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than 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 approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies with due diligence and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA currently requires, unless the sponsor is otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period, which could adversely impact the timing of the commercial launch of the product. In addition, breakthrough therapy designation is intended to expedite the development and review of therapeutics that treat serious or life-threatening conditions. The designation by the FDA requires preliminary clinical evidence that a therapeutic candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include (i) holding meetings with the sponsor and the review team throughout the development of the therapy, (ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable, (iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review, (iv) assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor and (v) considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same product if relevant criteria are met. If a product is designated as breakthrough therapy, FDA will expedite the development and review of such product.



Fast track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

In March 2021, we received fast track designation from the FDA for our non-genetically modified cryopreserved human placental hematopoietic stem cell-derived NK cell therapy.

### ***Post-Approval Requirements***

Any therapeutics 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 labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although a physician may prescribe a legally available product for an off-label use, if the physician deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. A company that is found to have promoted off-label use of its product may be subject to significant liability, including administrative, civil and criminal sanctions.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding 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, and those supplying products, ingredients, and components of them, are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our therapeutics under development.

### ***U.S. Marketing Exclusivity***

The Biologics Price Competition and Innovation Act, or BPCIA, amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if pediatric exclusivity is granted. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric trial that fairly responds to an FDA-issued "Written Request" for such a trial.

Depending upon the timing, duration and specifics of the FDA approval of the use of our therapeutic candidates, some of its U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for 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 restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved therapeutic is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent

and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond our current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

### ***Federal and State Licenses and Registrations***

The health care industry is subject to stringent regulation by a wide range of authorities. Accordingly, our business requires us to maintain certain licenses, registrations, permits, authorizations, approvals, certifications, accreditations and other types of federal, state, and local governmental permissions and to comply with various regulations in every jurisdiction in which we operate. For example, we are required to maintain licenses and registrations in several states, and has obtained biologics, tissue bank and blood bank licenses, permits and registrations in states where such licensure is required for us to market and support our products and services. Some states, such as New York, impose state law restrictions on products that have not been the subject of a BLA based upon their interpretation of guidance issued under federal law, including the FDA's guidance on HCT/Ps, which can lead to different, and potentially conflicting, regulatory frameworks applicable to our degenerative disease products on a state by state basis. We also maintain an annual registration with the FDA as a tissue bank, and national accreditation by the American Association of Blood Banks. The failure to comply with such licensure requirements can result in enforcement actions, including the revocation or suspension of the licenses, registrations or accreditations, or subject us to plans of correction, monitoring, civil money penalties, civil injunctive action and/or criminal penalties.

### ***Other U.S. Healthcare Laws and Compliance Requirements***

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (*e.g.*, the Office of Inspector General), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our business practices, including our research and sales, marketing and scientific/educational grant programs may be required to comply with the fraud and abuse provisions of the Social Security Act, false claims laws, anti-kickback and anti-bribery laws, the data privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, federal transparency requirements and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, either the referral of an individual for, or the purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below).

The federal civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have knowingly presented or caused to be presented a false or fraudulent claim to, among others, a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Further, violations of the Anti-Kickback Statute are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs.

The federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease

or conceal an obligation to pay money to the federal government, including federal healthcare programs. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the federal government. Pharmaceutical and other healthcare companies are being investigated or, in the past, have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, pharmaceutical and other healthcare companies also have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus non-reimbursable, uses. The federal False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the 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.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, imposes requirements on certain types of individuals and entities, including covered entities (*i.e.*, certain healthcare providers, health plans and healthcare clearinghouses), relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to business associates (and their subcontractors) that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions.

State laws also govern the privacy and security of personal information. Many state laws differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Privacy Act, or CCPA establishes data privacy rights for individuals located in California, and imposes certain requirements on how businesses can collect and use personal information about such individuals. The California Privacy Rights Act, or CPRA, which became effective on January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and significantly modifies the CCPA, including by expanding consumers’ rights with respect to certain sensitive personal information and establishes a state agency vested with the authority to enforce the CCPA. It is not yet fully clear how the CCPA (as amended by the CPRA) will be enforced and how it will be interpreted. The evolving nature of the CCPA may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply.

The CCPA (as amended by the CPRA) has prompted the enactment of similar, comprehensive privacy and data protection legislation in other states, such as Virginia, Colorado, Utah and Connecticut, which will all become effective in 2023. Furthermore, a number of other U.S. states have proposed similar privacy and data protection legislation, and it is possible that certain of these proposals will pass. Although many of the existing state privacy laws exempt clinical trial information and health information governed by HIPAA, future privacy and data protection laws may be broader in scope. Further, the proliferation of state privacy laws has heightened risks and uncertainties concerning our collection and use of personal information. This could lead to significant compliance costs and expenses on our business, increase our potential exposure to regulatory enforcement and/or litigation and have a negative effect on our ability to attract and retain new customers.

Additionally, the federal Physician Payments Sunshine Act created under the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, applicable manufacturers were also required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse-midwives.

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to

maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In order to distribute therapeutics commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states and local jurisdictions have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs and comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

### ***Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any therapeutic candidates for which we obtain regulatory approval. In the United States and certain markets in other countries, sales of any therapeutics for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. No uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process is often time-consuming and costly. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or from establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our therapeutics, in addition to the costs required to obtain the FDA approvals. Our therapeutic candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Net prices for our therapeutics may also be reduced by mandatory discounts or rebates required by government healthcare 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. Further, one payor's determination to provide coverage for a therapeutic does not assure that other payors will also provide coverage for the therapeutic. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in therapeutic development.

Different pricing and reimbursement schemes exist in other countries. In the European Union, or EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular therapeutic candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more



recent requirements in the Patient Protection Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply.

The marketability of any therapeutic candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. For example, actions by federal and state governments and health plans may put additional downward pressure on pharmaceutical pricing and health care costs, which could negatively impact coverage and reimbursement for our products if approved, our revenue, and our ability to compete with other marketed products and to recoup the costs of our research and development. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more therapeutics for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### ***Healthcare Reform***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell therapeutic candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP);
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- 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;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;

- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- a licensure framework for follow on biologic products.

There remains executive, legal and political challenges to certain aspects of the Affordable Care Act. For example, in December 2019, the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax, was signed into law. Moreover, the Bipartisan Budget Act of 2018, effective January 2019, among other things, amended the Affordable Care Act to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. In June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. Prior to the Supreme Court's decision an Executive Order was issued to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. The ultimate content, timing or effect of any healthcare reform legislation on the United States healthcare industry is unclear.

Previously, in October 2017, an Executive Order was signed terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. The former administration concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the Affordable Care Act have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California in October 2017. In August 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, in June 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in Affordable Care Act risk corridor payments to third-party payors who argued the payments were owed to them. In April 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved therapeutic, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our therapeutics. Such reforms could have an adverse effect on anticipated revenue from therapeutic candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop therapeutic candidates.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022. Then, a 1% payment reduction occurred beginning April 1, 2022 through June 30, 2022, and the 2% payment reduction resumed on July 1, 2022. Further, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

There has also been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. At the federal level, an Executive Order was signed in July 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices,



imposing inflation caps and supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs the Department of Health and Human Services, or HHS to provide a report on actions to combat excessive pricing of prescription drugs, to enhance the domestic drug supply chain, to reduce the price that the Federal government pays for drugs, and to address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations in September 2020, which went into effect in November 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, in November 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. In December 2021, CMS rescinded the Most Favored Nation rule. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our therapeutic candidates. Additionally, in December 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. In December 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 2026. The Inflation Reduction Act of 2022, or the IRA, further delayed implementation of this rule to January 2032.

In August 2022, the IRA was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a \$2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet known.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Executive branch may reverse or otherwise change these measures, both the current administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

### ***Additional Regulation***

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

### ***Europe/Rest of World Government Regulation***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our therapeutics. Whether or not we obtain FDA approval of a therapeutic, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the therapeutic in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit a Market Authorization Application. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of therapeutics, operating restrictions and criminal prosecution.

### **Employees and Human Capital Resources**

As of December 31, 2022, we had 225 full-time employees and 35 non-employee leased workers. Of these employees, 41 held Ph.D. or M.D. degrees, 35 were engaged in research, 12 were engaged in clinical development and 89 were engaged in technical operations. Substantially all of our employees are located in Florham Park, New Jersey. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good. In January 2023, we announced reprioritization of efforts which resulted in a reduction of approximately one-third of our workforce as of March 2023.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and additional employees. The principal purposes of our incentive plans are to attract, retain and motivate selected employees, consultants, and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

### **Available Information**

We post our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, free of charge, on the Investors section of our public website ([www.celularity.com](http://www.celularity.com)) as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, you can read our SEC filings over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). The contents of these websites are not incorporated into this annual report on Form 10-K. Further, our references to the URLs for these websites are intended to be inactive textual references only.

## Item 1A. Risk Factors.

*You should carefully consider the following risk factors, as well as the other information in this annual report on Form 10-K, and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.*

### **Risks Related to Business and Industry**

***We have incurred net losses in every period since our inception, have no cellular therapeutics approved for commercial sale and anticipate that we will incur substantial net losses in the future.***

We are a clinical-stage biopharmaceutical company, have no cellular therapeutics approved for commercial sale, have not generated any revenue from cellular therapeutic sales to date, generate limited revenues from our degenerative disease and biobanking businesses, and will continue to incur significant research and development and other expenses related to our ongoing operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential therapeutic candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. As a result, we are not profitable and have incurred net losses in each period since our inception. We reported net income of \$14.2 million and a net loss of \$100.1 million for the years ended December 31, 2022 and 2021, respectively. We had an accumulated deficit of \$645.5 million at December 31, 2022.

We expect to incur significant expenditures for the foreseeable future, and we expect these expenditures to increase as we continue our research and development of, and seeks regulatory approvals for, cellular therapeutic candidates based on our four placental-derived allogeneic cell types: CAR-T cells, unmodified NK cells, genetically modified NK cells, and MLASCs. Even if we succeed in commercializing one or more of our therapeutic candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional therapeutic candidates. In addition, we expect to incur costs in relation to our anticipated biomaterials product ramp-up to support our expansion outside of the United States with an initial focus on markets in the Middle East and North Africa. 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 from our cellular therapeutic candidates. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***Our historical operating results indicate substantial doubt exists related to our ability to continue as a going concern.***

We have incurred net losses and used significant cash in operating activities since inception, have no cellular therapeutic candidates approved for commercial sale and we anticipate that we will incur substantial net losses in the future. We have an accumulated deficit of \$645.5 million and have cash and cash equivalents of \$14.0 million as of December 31, 2022. Additionally, we are currently required to make monthly cash payments under our pre-paid advance agreement with Yorkville and do not have sufficient cash to meet such obligations. Unless our stock price improves or Yorkville waives the cash payment obligation, we could default under our obligation to Yorkville and it could accelerate the maturity of our repayment obligations, which would impact our liquidity and require us to cease or severely modify our operations or seek protection under the U.S. Bankruptcy Code. Accordingly, there is substantial doubt about our ability to continue as a going concern, which may affect our ability to obtain future financing and may require us to further curtail our operations. For additional details, see the discussion under "Overview—Going Concern" in Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations." We will need to raise additional capital to support our operations. This additional funding may not be available on acceptable terms or at all. Failure to obtain this necessary capital or address our liquidity needs may force us to delay, limit or terminate our operations, make further reductions in our workforce, discontinue our commercialization efforts for our biomaterials products as well as other clinical trial programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

***We will need substantial additional financing to develop our therapeutics and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our therapeutic candidates.***

We expect to spend a substantial amount of capital in the development and manufacture of our therapeutic candidates. We will need substantial additional financing to develop our therapeutics and implement our operating plans. In particular, we will require substantial additional financing to enable commercial production of our therapeutics and initiate and complete registration trials for multiple cellular therapeutics. Further, if approved, we will require significant additional amounts in order to launch and commercialize our therapeutic candidates.

As of December 31, 2022, we had \$14.0 million in cash and cash equivalents. We will need to raise additional capital to implement our plans. Further, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we

may need to spend more money than currently expected because of circumstances beyond our control. We may also need to raise a large amount of capital sooner than currently anticipated if we choose to expand more rapidly than our present plans. In any event, we will require additional capital for the further development and commercialization of our therapeutic candidates, including funding our internal manufacturing capabilities and growth of our degenerative disease business.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our therapeutic candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations under the agreements, including our license from Sorrento. We could be required to seek collaborators for our therapeutic 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 therapeutic candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our securities to decline.

***Our placental-derived cellular therapy candidates represent a novel approach to cancer, infectious and degenerative disease treatments that creates significant challenges.***

We are developing a pipeline of allogeneic cellular therapeutic candidates that are derived from healthy, full-term, human donor placentas, and in certain cases, are genetically modified. Allogeneic cells are intended to be “off-the-shelf” for use in any patient. Advancing these novel therapeutic candidates creates significant challenges, including:

- manufacturing cellular therapeutic candidates to our and regulatory specifications and in a timely manner to support our clinical trials, and, if approved, commercialization;
- biosourcing placentas and other materials and supplies for the manufacture of our therapeutic candidates;
- any variability in placental-derived cells, or a higher-rejection rate, which could ultimately affect our ability to produce therapeutics in a reliable and consistent manner and treat certain patients;
- educating medical personnel regarding the potential advantages and potential disadvantages such as the side effect profile of our therapeutics, if approved, such as the potential adverse side effects related to GvHD, cytokine release syndrome, or CRS, neurotoxicity, prolonged cytopenia and neutropenic sepsis;
- using medicines to manage adverse side effects of our therapeutic candidates that may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;
- obtaining regulatory approval, as the FDA, and other regulatory authorities have limited experience with development of allogeneic cell therapies for cancer, infectious and degenerative diseases; and
- establishing sales and marketing capabilities for our therapeutic portfolio upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

***The gene-editing technology we use is relatively new, and if we are unable to use this technology in our intended therapeutic candidates, our revenue opportunities will be materially limited.***

We use gene editing techniques to modify certain of the placental-derived cell types. We use these technologies to either reduce the risk of toxicity or improve the potential for efficacy. These technologies are relatively new, and may not be shown to be effective at achieving the expected effect in clinical studies, or may be associated with safety issues, either in our clinical development programs or those of others using these novel technologies. Any issues with the novel gene editing technologies, even if not experienced by us, could negatively affect our development programs. For instance, the genetic modifications may create unintended changes to the DNA, such as a non-target site gene-editing, a large deletion, or a DNA translocation, any of which could lead to unwanted side-effects. The gene-editing of our therapeutic candidates may also not be successful in limiting the risk of GvHD or thrombosis or in increasing affinity.

Some competitors in the allogeneic cell therapy space and more broadly in the gene therapy space have had clinical trials put on hold by the FDA. Based on findings in those clinical trials, the FDA may request additional testing, request different types of testing or even substantially revise the methodology used to evaluate clinical trials for other companies pursuing similar therapeutic avenues. We cannot control the actions of our competitors, cannot influence the results of their clinical trials and cannot know how FDA may react to a specific fact pattern arising in another clinical trial. Additional testing, different types of testing or a revised regulatory approach may delay our clinical trials, increase costs in our trials or otherwise preclude our trial from being given permission to proceed absent substantial time, effort and resources on our part. For example, in the first quarter of 2022, we submitted an IND to investigate CYCART-19 for treatment of B-cell malignancies and in late May 2022, received formal written communication from FDA requesting



additional information before we can proceed with the planned Phase 1/2 clinical trial. We are in the process of working with the FDA in an effort to resolve its questions.

In addition, the gene-editing industry is rapidly developing, and our competitors may introduce new technologies that render the technologies that we employ for our therapeutic candidates obsolete or less attractive. New technology could emerge at any point in the development cycle of our therapeutic candidates. As competitors use or develop new technologies, any failures of such technology could adversely impact our programs. We also may be placed at a competitive disadvantage, and competitive pressures may force us to implement new technologies at a substantial cost. In addition, our competitors may have greater financial, technical and personnel resources that allow them to enjoy technological advantages and may in the future allow them to implement new technologies before we can. We cannot be certain that we will be able to implement technologies on a timely basis or at an acceptable cost. If we are unable to maintain technological advancements consistent with industry standards, our operations and financial condition may be adversely affected.

***We rely on CAR-T viral vectors from Sorrento Therapeutics, Inc. for our CYCART-19 therapeutic candidate and termination of this license, or any future licenses, could result in the loss of significant rights, which would harm our business.***

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. In order to modify the placental-derived T cells to produce our CAR-T cell line, and our CYCART-19 therapeutic candidate, we use retroviral technology licensed from, and supplied by, Sorrento. We depend substantially on our license agreement with Sorrento. This license may be terminated by Sorrento for our uncured material breach. Any termination of this license could result in the loss of significant rights and could harm our ability to commercialize CYCART-19, and any future therapeutic candidates that use the licensed CAR construct. To the extent that obligations under this license agreement are not met, we may lose the benefits of the Sorrento license agreement and the CAR construct we use for CYCART-19. Further, we would need an additional license from Sorrento or access to other CAR construct technology to research and develop therapeutic candidates directed at targets not covered by our existing agreement with Sorrento. In addition, the Sorrento CAR-T retroviral technology may fail to produce viable therapeutic candidates. If we were to obtain approval of CYCART-19, there is no assurance that Sorrento would be able to supply sufficient viral vectors for commercial-scale manufacturing. If the agreement with Sorrento was terminated or we required other technology, such a license or technology may not be available to us on reasonable terms, or at all, particularly given the limited number of alternative technologies in the market. See Item 1 “*Business — Licensing Agreements — Sorrento Therapeutics, Inc.*” for more information regarding the license from Sorrento. On February 13, 2023, Sorrento announced that it commenced voluntary proceedings under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of Texas. At this time, we cannot predict what impact the bankruptcy will have on Sorrento’s continued ability to perform under the license agreement.

We also use other gene editing technology for the other cellular therapeutics in our pipeline. While certain of these technologies are available from multiple commercial vendors, were any of these vendors to refuse to supply us, it could negatively impact our development of our modified NK cells and MLASCs, which depend on genetic modification to achieve the intended clinical benefits. Moreover, some gene editing technology that is currently available without license, could become patented or proprietary to a third party. If we are unable to obtain a license on commercially reasonable terms when needed, we could be forced to redesign our cellular therapeutics and or stop development. Any of these occurrences could have a material adverse effect on our business prospects.

Disputes may also arise between us and our current and future licensors regarding intellectual property subject to a license agreement, including those related to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our therapeutic candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed, or may license in the future, prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected therapeutic candidates.



We are generally also subject to all of the same risks with respect to protection of intellectual property that our licenses, as it is for intellectual property that we own, which are described below. If we or our current and future licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

***Our therapeutic candidates are based on novel technologies, which makes it difficult to predict the time and cost of therapeutic candidate development and obtaining regulatory approval.***

We have concentrated our research, development and manufacturing efforts on our placental-derived allogeneic T cell, NK cell and MLASC therapeutic candidates, and our future success depends on the successful development of these therapeutic approaches. We have developed our Celularity IMPACT platform, which covers biosourcing through manufacturing of cryopacked cells, and continues to invest in optimizing and improving our technologies. There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. We may also experience delays in scaling our manufacturing process when appropriate for commercialization, which may prevent us from completing our clinical studies or commercializing our therapeutics on a timely or profitable basis, if at all. In addition, as we are in the early stages of clinical development, we do not know the doses to be evaluated in pivotal trials or, if approved, commercially. Finding a suitable dose for our cell therapeutic candidates may delay our anticipated clinical development timelines. In addition, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our therapeutic candidates and understand these critical factors.

The clinical study requirements of the FDA, European Medicines Agency, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a therapeutic candidate are determined according to the type, complexity, novelty and intended use and market of the potential therapeutics. The regulatory approval process for novel therapeutics candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other therapeutic candidates. In addition, under guidelines issued by the NIH, gene therapy clinical trials are also subject to review and oversight by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, that institution's IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH guidelines voluntarily follow them.

While we expect reduced variability in our allogeneic cell therapeutic candidates compared to autologous products, we do not have significant clinical data supporting any benefit of lower variability and the use of healthy donor full-term placentas, and related screening requirements, may create separate variability challenges. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new therapeutic candidates. Moreover, our therapeutic candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the autologous therapies that have previously been approved. For instance, allogeneic T cell therapeutic candidates may result in GvHD not experienced with autologous T cell products. While we have modified our CAR-T cell candidate to attempt to address this concern, CYCART-19 may still be associated with GvHD and may not be effective in clinical trials. Even if we collect promising initial clinical data of our therapeutic candidates, longer-term data may reveal new adverse events or responses that are not durable. Unexpected clinical outcomes would significantly impact our business.

***Our business is highly dependent on the success of our lead therapeutic candidates. If we are unable to obtain approval for our lead candidates and effectively commercialize our lead therapeutic candidates for the treatment of patients in approved indications, our business would be significantly harmed.***

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully commercialize, our most advanced therapeutic candidates, including CYCART-19, CYCART-201, CYNK-001, CYNK-301, CYNK-302, APPL-001 and pEXO-001. Because these placental-derived allogeneic cells are among the first allogeneic placental-derived cell therapies to be evaluated in the clinic, the failure of any such therapeutic candidate, or the failure of other allogeneic cell therapies, may impede our ability to develop our therapeutic candidates, and significantly influence physicians' and regulators' opinions in regards to the viability of our entire pipeline of placental-derived allogeneic cell therapies, particularly if high or uncontrolled rates of GvHD or other adverse events are observed. If significant adverse events are observed with the administration of our therapeutic candidates, or if any of the therapeutic candidates is viewed as less safe or effective than autologous therapies, our ability to develop other placental-derived allogeneic therapies may be significantly harmed.

All of our therapeutic candidates, including our lead therapeutic candidates, will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, scaled commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from sales of our cellular therapeutics. In addition, because our therapeutic candidates are all based on a similar process, our Celularity IMPACT platform, if any of the lead therapeutic candidates encounters safety or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business for our therapeutics pipeline would be significantly harmed.

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

Undesirable or unacceptable side effects caused by our therapeutic candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous cell therapies and those under development have shown frequent rates of CRS and neurotoxicity, and adverse events have resulted in the death of patients. Certain of our therapeutic candidates, such as CYCART-19, CYCART-201, CYNK-301, CYNK-302 and APPL-001 undergo genetic engineering. As these are novel technologies, errors may occur or may not present until used in humans in the clinic, and could cause adverse events. While we believe that placental-derived cells, including our use of NK cells and MLASCs, have an inherent safety profile that may limit adverse events, there can be no assurance that this is the case as these are novel therapeutics.

As we continue to evolve our placental-derived therapeutic programs, we may need to halt or modify development of certain candidates as a result of adverse events. For example, in designing APPL-001, we made certain modifications and adjustments, including a genetic modification due to an increased risk of thrombosis observed in a Phase 1 clinical trial of a legacy placental-derived MLASC done at Celgene Cellular Therapeutics.

In any of our ongoing or planned clinical trials, patients may experience severe adverse events related to our allogeneic cell therapeutic candidates, some of which may result in death. If unacceptable toxicities arise in the development of our therapeutic candidates, we could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our therapeutic candidates for any or all targeted indications. The data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from cell therapy are not normally encountered in the general patient population and by medical personnel. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

Before obtaining regulatory approvals for the commercial sale of our cell therapeutic candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our therapeutic candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and our 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 therapeutic candidates may not be predictive of the results of later-stage clinical trials, including in any post-approval studies.

There is typically an extremely high rate of attrition from the failure of therapeutic candidates proceeding through clinical trials. Therapeutic 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. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most therapeutic candidates that commence clinical trials are never approved as therapeutics.

In addition, for ongoing and any future trials that may be completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, including, for example, any re-analysis of legacy data that we perform, and more trials could be required before we submit our therapeutic 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, approval of our therapeutic candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our therapeutic candidates.

***Initial, interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

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

***We may not be able to submit INDs to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit such trials to proceed.***

We plan to submit INDs for additional therapeutic candidates in the future including one planned in 2023 for an extracellular matrix biomaterials product candidate. We cannot be certain that submission of an IND or IND amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. For example, we submitted an IND for CYCART-19 for the treatment of B-cell malignancies in 2022, and we continue to work with FDA to resolve its questions as promptly as possible, which we must do before initiating clinical trials under this IND. The manufacturing of allogeneic cell therapies remains an emerging and evolving field. Accordingly, we expect chemistry, manufacturing and control related topics, including product specification, will be a focus of IND reviews, which may delay the clearance of INDs. Additionally, even if FDA permits the initiation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that FDA will not change our requirements in the future.

***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 studies will be conducted as planned or completed on schedule, if at all. Even if our trials begin as planned, issues may arise that could cause us or relevant regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies 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 studies;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- difficulty sourcing healthy full-term donor placentas of sufficient quality and in sufficient quantity to meet our development needs;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain therapeutic candidates;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required IRB approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons;
- delays in patient recruitment, and or difficulty collaborating with patient groups and investigators, or other issues involving patient, such as completing participation or return for post-treatment follow-up, or dropping-out;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's GCP requirements or applicable regulatory guidelines in other countries;
- issues with manufacturing of cellular therapeutics, including delays in manufacturing, testing, releasing, validating sufficient stable quantities of our therapeutic candidates for use in clinical studies or the inability to do any of the foregoing;
- occurrence of adverse events associated with the therapeutic 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 studies of our therapeutic candidates being greater than we anticipate;
- negative or inconclusive results from clinical studies, which may result in us deciding, or regulators requiring us, to conduct additional clinical studies or abandon development programs; and

- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet its quantity or quality requirements for necessary raw materials.

The ongoing COVID-19 pandemic, including the resurgence of cases relating to the spread of the newly emerging variants, or future pandemics, may also increase the risk of certain of the events described above and delay our development timelines. For example, in early 2020 and again in mid-2021, we experienced delays in enrolling our Phase 1 clinical trial of CYNK-001 for AML as a result of the pandemic. 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 therapeutic candidates, we may be required to, or we may elect to conduct additional studies to bridge our modified candidates to earlier versions or may need to conduct additional studies on newly discovered candidates. Clinical study delays could also shorten any periods during which our therapeutics have patent protection and may allow our competitors to bring cell therapies to market before we do, which could impair our ability to successfully commercialize our therapeutic candidates and may harm our business and results of operations.

***Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic and future outbreaks of the disease, in regions where we or third parties on which we relies have concentrations of clinical trial sites or other business operations.***

Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic and future outbreaks of the disease. For example, enrollment in clinical trials of CYNK-001 for AML was delayed due to the COVID-19 outbreak. Additionally, our ability to collect healthy, full-term donor placentas was limited during the height of the COVID-19 pandemic in New Jersey and the tri-state area as hospital resources were diverted. Although we have reopened our offices and employees have transitioned back to working on site, there is a lack of uniformity of restrictions and requirements among our clinical trial sites, and future shelter-in-place or similar type restrictions could be reimposed, and once again, hospital personnel may not pursue donor consents. We are now also subject to risk of outbreaks at our facilities, and potential exposure to employee claims regarding workplace safety, and unanticipated shutdowns or quarantines could be imposed in the future, which would disrupt our operations. This uncertainty and the evolving nature of policies and restrictions, may negatively impact productivity, disrupt our business and further delay clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course, which could negatively impact our business, operating results and financial condition.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it has resulted in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our Class A common stock.

The global COVID-19 pandemic continues to evolve, and our ultimate impact or that of any similar health pandemic or epidemic is highly uncertain. We do not yet know the full extent of potential delays or impacts on our business, our planned and ongoing clinical trials, the hospitals and healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

***Monitoring and managing toxicities in patients receiving therapeutic candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize our therapeutic candidates.***

We expect to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials to monitor patients for GvHD (for CYCART-19), in addition to more generally monitoring patients for adverse events who participate in our clinical trials. Even with these procedures in place, these centers and hospitals may have difficulty observing patients and treating toxicities or any other adverse events, which could lead to more severe or prolonged toxicities or even patient deaths. If there are any serious issues with GvHD or any other unanticipated events, it could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, which could jeopardize regulatory approval of our therapeutic candidates. Moreover, to the extent our cellular therapies are used outside of hospitals or medical centers, and upon any approval if our therapies are made more widely available on a commercial basis, it may become even more difficult to observe and manage adverse events. Moreover, medicines used at centers to help manage adverse side effects of our therapeutic candidates, such as any GvHD, may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment.

***Clinical trials are expensive, time-consuming and difficult to design and implement.***

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our allogeneic placental-derived cell therapeutic candidates are based on new technologies and will require the creation of inventory of mass-produced, off-the-shelf therapeutics, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with certain cancers or other targeted



indications, including treating any potential side effects, could be significant. Accordingly, our clinical trial costs for our cellular therapeutic candidates are likely to be significantly higher than for more conventional therapeutic technologies or drug products.

***If we fail to develop additional therapeutic candidates, our commercial opportunity will be limited.***

One of our core strategies is to pursue clinical development of additional therapeutic candidates beyond our initial seven key programs, CYCART-19, CYCART-201, CYNK-001, CYNK-301, CYNK-302, APPL-001 and pEXO-001, and to expand beyond the initial six indications targeted. Developing, obtaining regulatory approval and commercializing additional cell therapeutic candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide any assurance that we will be able to successfully advance any of these additional therapeutic candidates through the development process.

Even if we receive FDA approval to market these or additional therapeutic candidates, we cannot assure any such therapeutic candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional therapeutic candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional therapeutic candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, therapeutic candidate.

***Our recent organizational changes and cost cutting measures may not be successful.***

In November 2022 and January 2023, we implemented reduction-in-force affecting a majority of our workforce. The objective of this workforce reduction was to realign our workforce to meet our needs in light of the results we received in clinical trials and the ongoing evaluation of clinical development plans. However, these restructuring and cost cutting activities may yield unintended consequences and costs, such as attrition beyond our intended reduction-in-force, a reduction in morale among our remaining employees, and the risk we may not achieve the anticipated benefits of the such reduction-in-force measure, all of which may have an adverse effect on our results of operations or financial condition. In addition, while positions have been eliminated, certain functions necessary to our reduced operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. We may also discover the reductions in workforce and cost cutting measures will make it difficult for us to resume development activities we have suspended or pursue new initiatives, requiring us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. As a result of the loss of services of substantially all of our personnel, including several of our executive officers, we may be unable to continue our operations and meet our ongoing obligations. Any of these unintended consequences may have a material adverse impact on our business, financial condition, and results of operations.

***We operate our own manufacturing and storage facility, which requires significant resources; manufacturing or other failures could adversely affect our clinical trials and the commercial viability of our therapeutic candidates and our biobanking and degenerative diseases businesses.***

We have a purpose-built facility located in Florham Park, New Jersey, where we process healthy full-term donor placentas for use in cell therapy and tissue products and operate our biobanking business. While we have experience managing the process for our research and existing clinical trial needs, we may not be able to mass-produce off-the-shelf placental-derived allogeneic cellular therapeutics to satisfy demands for any of our therapeutic candidates as we expand into later stage clinical trials, or for commercial production post-approval. While we believe the manufacturing and processing approaches are appropriate to support our current needs and that we have a scalable process and have secured appropriate supply from various third-parties, including Sorrento, we cannot be sure that our scaled process will result in allogeneic cells that will be safe and effective. Further, our manufacturing and storage facility, including for our biobanking and degenerative disease businesses, must comply with cGMP, which includes, as applicable, the FDA's current GTPs for the use of human cellular and tissue products. Accordingly, we are subject to ongoing periodic unannounced inspection by the FDA and other governmental agencies to ensure strict compliance with cGMP, including GTPs as applicable, and other government regulations.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The application of new regulatory guidelines or parameters, such as those related to release testing, may also adversely affect our ability to manufacture our therapeutic candidates. Furthermore, if contaminants are discovered in our supply of therapeutic candidates or in the manufacturing facilities, such supply may have to be discarded and our manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure any stability or other issues relating to the manufacture of our therapeutic candidates will not occur in the future.



We or any other of our vendors may fail to manage the logistics of storing and shipping our raw materials, including donor placentas. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, health pandemics or epidemics, could result in the inability to manufacture therapeutics, the loss of usable therapeutics or prevent or delay the delivery of therapeutic candidates to patients and clinical trial sites. We may also experience manufacturing difficulties due to resource constraints or as a result of labor disputes. If we were to encounter any of these difficulties, our ability to provide our therapeutic candidates to patients would be jeopardized.

***We currently have no cellular therapeutics marketing sales force. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our therapeutic candidates once approved, we may not be able to generate product revenue.***

We currently have no sales, marketing or distribution capabilities and, as a company, have no experience in marketing cellular therapeutics as our current sales force is limited to our degenerative disease and biobanking businesses. We intend to develop an in-house specialized marketing organization and sales force for our cellular therapeutic candidates, if such candidates receive regulatory approval, which will require significant 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 distribution capabilities for our cellular therapeutics once approved, we will pursue collaborative arrangements regarding the sales and marketing of cellular therapeutics; 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 from the sale of cellular therapeutics 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 therapeutic sales may be lower than if we had commercialized our therapeutic candidates directly, as we do for our degenerative disease products and biobanking business. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our therapeutic candidates. There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any therapeutic that receives regulatory approval in the United States or in other markets.

***A variety of risks associated with conducting research and clinical trials abroad and marketing our therapeutic candidates internationally could materially adversely affect our business.***

We plan to globally develop our therapeutic candidates and market our degenerative disease products outside the United States. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- differing standards for the conduct of clinical trials;
- increased difficulties in managing the logistics and transportation of storing and shipping therapeutic candidates or biomaterials produced in the United States and shipping the therapeutic candidate to the patient abroad, which may necessitate local or regional manufacture, including the need to source healthy full-term donor placentas outside the United States;
- import and export requirements and restrictions, including as they pertain to donor placentas and human tissue collection and manufacture;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;

- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply, including obtaining sufficient donor placentas, and other issues with manufacturing abroad; and
- business interruptions resulting from the COVID-19 pandemic or other natural or man-made disasters, including earthquakes, tsunamis, fires or other medical epidemics, or geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

***Because we have multiple programs and therapeutic candidates in our development pipeline and are pursuing a variety of target indications, we may expend our limited resources to pursue a particular therapeutic candidate and fail to capitalize on development opportunities or therapeutic candidates that may be more profitable or for which there is a greater likelihood of success.***

We are focused on the development of cellular therapeutic candidates, targeting indications across cancer, infectious and degenerative diseases. Because we have limited financial and personnel resources, we may forgo or delay pursuit of opportunities with potential target indications or therapeutic candidates that later prove to have greater commercial potential than our current and planned development programs and therapeutic candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future therapeutic candidates for specific indications may not yield any commercially viable future therapeutic candidates. If we do not accurately evaluate the commercial potential or target market for a particular therapeutic candidate, we may be required to relinquish valuable rights to that therapeutic candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future therapeutic candidates.

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

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds, drugs or biomaterials that are able to achieve similar or better results. Our potential competitors for our cellular therapeutics and biomaterials include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our therapeutic candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Even if we obtain regulatory approval of our therapeutic candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our therapeutic candidates. We may not be able to implement our business plan if the acceptance of our therapeutic candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our therapeutic candidates, or if physicians switch to other new drug or biologic products or choose to reserve our therapeutic candidates for use in limited circumstances. For additional information regarding our competition, see the section entitled "Business — Competition."

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Founder and Chief Executive Officer, Robert Hariri, M.D., Ph.D., our Chief Operating Officer, Brad Glover, Ph.D. and our Chief Medical Officer, Adrian Kilcoyne, MD. The loss of the services of any of our executive officers, other key

employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. We conduct substantially all of our operations at our facilities in New Jersey. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Despite efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave employment at any time, with or without notice. We do not maintain “key person” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

***We may experience difficulties in managing the growth of our business.***

As of December 31, 2022, we had 225 full-time employees and 35 non-employee leased workers. As our development and commercialization plans and strategies developed, and as we began operations as a public company following the Business Combination, we expanded our employee base and expect to add managerial, operational, sales, research and development, marketing, financial and other personnel. Subsequently, in November 2022 and January 2023, we implemented reduction-in-force affecting a majority of our workforce as part of reprioritization efforts to achieve our strategic objectives.

Current and future growth imposes significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA review process for our therapeutic candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our therapeutic candidates will depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop, manufacture and commercialize our therapeutic candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals.

***We may form or seek 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 therapeutic candidates and any future therapeutic 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 stockholders or disrupt our management and business. We licensed certain intellectual property back to Celgene in connection with the Anthrogenesis acquisition. Given the broad scope of the license, Celgene could use our intellectual property to develop therapeutics that compete with us in the CAR field. Additionally, we have continuing obligations to Celgene under the CVR Agreement, under which we may be required to make certain payments to Celgene with respect to certain of our therapeutics, including CYNK-001, CYNK-301 and CYNK-302. Our payment obligations to Celgene under the CVR Agreement may limit our ability to partner such assets, were we choose to do so. See Item 1 “Business — Our Team and Corporate History — Celgene Corporation” for more information regarding the Celgene relationship.

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 therapeutic 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 therapeutic candidates as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements related to our therapeutic candidates could delay the development and commercialization of our therapeutic candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We have in the past and in the future will continue to explore entering into new strategic alliances, collaborations, and licensing arrangements with third parties related to non-core areas. Such arrangements are entered into based on information available at the relevant time, and may not lead to long-term collaborations after initial research and development is conducted. We are party to certain agreements, and may in the future enter into new agreements, that contain non-competes or otherwise restrict our ability to operate in a particular field.

Further, disputes may arise under our current or future strategic alliances, collaborations, or other agreements or arrangements that include grants of intellectual property rights to or from us, or payments related thereto, including disagreements over scope of rights granted, proprietary rights, payment obligations, contract interpretation or the preferred course of research, development or commercialization. As a result of such disagreements, we may be required to pay additional amounts, there may be a reduction or delay in amounts payable to us, or there may be delays in research, development or commercialization activities, or termination of the arrangements, which could adversely impact our business and operations.

If we license 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. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

***We may not realize the benefits of acquired assets or other strategic transactions.***

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, including our license with Sorrento, and any future strategic transactions depends on the risks and uncertainties involved, including:

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in our relationships with collaborators or suppliers as a result of such a transaction; and
- possible write-offs or impairment charges relating to acquired businesses or joint ventures.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition.

***Our internal computer systems, or those used by our CROs, collaborators or other contractors or consultants, may fail or suffer security breaches.***

Our internal computer systems and those of our CROs, collaborators, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, cybersecurity threats, and telecommunication and electrical failures. Cyber-attacks, denial-of-service attacks, ransomware attacks, business email compromises, computer malware, viruses, and social engineering (including phishing) continue to increase generally. Accordingly, if our cybersecurity measures or those of our service providers fail to protect against unauthorized access, attacks (which may include sophisticated cyberattacks), compromise or the mishandling of data by our employees or contractors, then our reputation, customer trust, business, results of operations and financial condition could be adversely affected. Cyber incidents have been increasing in sophistication and can include third parties gaining access to sensitive data using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks, ransomware, card skimming code, and other deliberate attacks and attempts to gain unauthorized access. The techniques used to sabotage or to obtain unauthorized access to our internal computer systems in which data is stored or through which data is transmitted change frequently, and we may be unable to implement adequate preventative measures or stop security breaches while they are occurring. Because the techniques used by threat actors who may attempt to penetrate and sabotage our computer systems change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques. While 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. To the extent that any disruption or security breach in our systems or infrastructure (including provided by third party vendors) 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 therapeutic candidates could be delayed. In addition, our increased reliance on personnel working from home could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business. As an early-stage company without



significant investments in data security protection, we may not be sufficiently protected against such occurrences, and may not have the resources to allocate to such efforts.

***Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new therapeutics and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new therapeutics can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, statutory, regulatory and policy changes, and business disruptions, such as those caused by the COVID-19 pandemic. Average review times at the agency have fluctuated in recent years as a result. In addition, funding of government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics 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 has had to furlough critical employees and stop critical activities. In addition, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold as a result of the COVID-19 pandemic, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or disruption occurs, it could significantly impact the ability of the FDA or other regulatory authorities 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.

***Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.***

In addition to the business disruptions and clinical trial delays caused by the COVID-19 pandemic described above, our operations, and those of our CROs and other contractors and consultants, could be subject to other disruptions, including those caused by power shortages, telecommunications failures, water shortages, floods, hurricanes, tornadoes, fires, earthquakes, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to manufacture our therapeutic candidates could be disrupted if our operations or those of our suppliers are affected by a man-made or natural disaster or other business interruption. Moreover, because our core operations are concentrated at our purpose-built facility in Florham Park, New Jersey, any disruptions at this site, if prolonged, could materially harm our business and prospects.

***If we do not obtain and maintain federal and state licenses and registrations required for our current and future operations, our ability to generate revenue will be limited.***

The health care industry is subject to stringent regulation by a wide range of authorities. Accordingly, our business requires us to maintain certain licenses, registrations, permits, authorizations, approvals, certifications, accreditations and other types of federal, state, and local governmental permissions and to comply with various regulations in every jurisdiction in which we operate. For example, we are required to maintain licenses and registrations in several states, and have obtained biologics, tissue bank and blood bank licenses, permits and registrations in states where such licensure is required for us to market and support our products and services. We also maintain an annual registration with the FDA as a tissue bank, and national accreditation by the American Association of Blood Banks. The failure to comply with such licensure requirements can result in enforcement actions, including the revocation or suspension of the licenses, registrations or accreditations, or subject us to plans of correction, monitoring, civil money penalties, civil injunctive action and/or criminal penalties. While we believe that, given our current and proposed business, we are not presently required to obtain additional licenses or registrations to market our products or services, we cannot predict whether additional regulatory approval will be required in the future and, if so, whether such approval will at such time be obtained, whether for the stem cells and/or any other services that we are developing or may attempt to develop. Our failure to obtain and maintain required federal and state licenses and registration will limit our ability to generate revenue.



***Our relationships with customers, physicians, and third-party payors are subject to numerous laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.***

We operate in a highly regulated industry, and our relationships with customers, physicians, and third-party payors are subject to numerous laws and regulations. See the section entitled “*Business — Government Regulation and Product Approval – Other U.S. Healthcare Laws and Compliance Requirements*”. Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain marketing approval. Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may impact, among other things, our clinical research and development programs, as well as our proposed and future sales, marketing and education programs for our cellular therapeutics, as well as the sales and marketing of our degenerative disease products and biobanking business. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations 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, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, some of whom may receive stock options as compensation for service on our scientific advisory board, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions or significant penalties. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct 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 be in compliance with such laws or regulations. 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 are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties and corrective measures, 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 therapeutic candidates or our degenerative disease products outside the United States will also likely subject us to an additional overlay of foreign equivalents of the healthcare laws, among other foreign laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company’s attention from the business.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

***Our collection, use, processing, and cross-border transfer of personal information, including individually identifiable health information, is governed by restrictive regulations.***

Our business is broadly regulated by U.S. and foreign regulatory authorities, and we must comply with all applicable rules and regulations concerning our use, processing, handling, maintenance, and protection of personal information. In the U.S., HIPAA imposes requirements at the federal level relating to the privacy, security and transmission of individually identifiable health information, while individual states, such as California and Virginia, have adopted privacy regulations restricting the use of personal information and providing individuals certain rights with respect to the collection and use of their data. See Item 1 “*Business — Other U.S. Healthcare Laws and Compliance Requirements*” for more information regarding U.S. privacy and data protection laws. Further, the collection and use of personal information in Europe is governed by the EU’s General Data Protection Regulation and the United Kingdom’s implementation of the same, or the GDPR. Failure to comply with the requirements of the GDPR and other applicable data protection laws of the EU member states and the United Kingdom, or other applicable privacy rules and regulations in other countries, may result in significant fines and other administrative penalties. We may be required to put in place additional mechanisms to comply with current and future privacy and data protection regulations applicable to our business. This may interrupt or delay our development activities and/or require us to change our business practices, which could adversely affect our business, financial condition, results of operations and prospects.

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

We face an inherent risk of product liability as a result of the clinical testing of our therapeutic candidates and will face an even greater risk if we commercialize any cellular therapeutics, in addition to the risks from the sale of our degenerative disease products. For example, we may be sued if our therapeutic candidates or degenerative disease products 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 therapeutic or product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our therapeutic candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in a number of adverse effects, any of which could materially harm our financial condition and results of operations.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of therapeutics we develop, alone or with corporate collaborators, or negatively impact our degenerative disease business. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. While we have obtained and expect to obtain clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

### **Risks Related to Our Reliance on Third Parties**

***We rely and will continue to 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, we may not be able to obtain regulatory approval of, or commercialize, our therapeutic candidates.***

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical and clinical trials. We negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for therapeutic candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail 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 clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biological product produced under cGMP 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 studies or other drug development activities, which could affect their performance. 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 therapeutic candidates. As a result, our financial results and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition

period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

***We rely on donors of healthy human full-term placentas to manufacture our therapeutic candidates, and if we do not obtain an adequate supply of such placentas from qualified donors, development of our placental-derived allogeneic cells may be adversely impacted.***

We are reliant on biosourcing healthy donor placentas to manufacture our therapeutic candidates, and on hospital personnel to obtain the necessary donor consent. Healthy donor placentas vary in type and quality, and this variation makes producing standardized therapeutic candidates more difficult and makes the development and commercialization pathway of our therapeutic candidates more uncertain. We have developed a process designed to enhance the quality and consistency of the placental-derived cells used in the manufacture of our three allogeneic cell types (CAR-T cells, NK cells and mesenchymal-like stromal cells), but our process may fail to identify suitable donors or detect all issues, and we may discover failures with the material after production. We may also have to update our specifications for new risks that may emerge, such as to screen for new viruses.

We have strict specifications for donor material, which include specifications required by regulatory authorities and rely on informed donor consent. If we are unable to identify and obtain donor material that satisfy specifications, agree with regulatory authorities on appropriate specifications, incentivize hospital personnel to solicit consent to donation or address variability in donor placentas, there may be inconsistencies in the therapeutic candidates we produce or we may be unable to initiate or continue ongoing clinical trials on the timelines we expect, or scale up our manufacturing process for later-stage clinical trials or commercialization, which could harm our reputation and adversely impact our business and prospects.

***Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.***

Our therapeutic candidates require many specialty raw materials, including viral vectors that deliver the CAR sequence from Sorrento, and other raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial therapeutic, or to deliver raw materials to our specifications. Although we are currently negotiating a supply agreement with Sorrento, we generally do not have dedicated supply contracts with many of our suppliers, and we may not be able to contract with them on acceptable terms, or at all. Many suppliers curtailed their operations during the COVID-19 pandemic and our ability to source raw materials has been impacted. Further, some of our suppliers may not be able to scale-up as we move to later-stage clinical trials or commercialization. Accordingly, we may experience delays in receiving, or fail to secure entirely, key raw materials to support clinical or commercial manufacturing. Certain raw materials also require third-party testing, and some of the testing service companies may not have capacity or be able to conduct the testing that we request.

We also face competition for supplies from other cell therapy companies. Such competition may make it difficult for us to secure raw materials or the testing of such materials on commercially reasonable terms or in a timely manner.

Some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier, including to meet any regulatory requirements for such qualification, could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

***If we or third party suppliers acting on our behalf use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development and manufacturing activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We 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 our procedures, as well as the procedures of our third party suppliers for using, handling, storing and disposing of these materials comply with legally prescribed standards, neither we nor our third party suppliers can 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 our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have 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 our business, prospects, financial condition or results of operations.

## **Risks Related to Government Regulation**

***The FDA regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our therapeutic candidates.***

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, 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 approval of a biologics license application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the therapeutic candidate's safety and effectiveness for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product.

We expect the novel nature of our therapeutic candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of allogeneic cell therapies. We may also request regulatory approval of future therapeutic candidates by target, regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involved cancers of certain origins. 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 therapeutic candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our therapeutic candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing planned clinical trials for a variety of reasons, including if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our therapeutic candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors. The FDA's review of our data for ongoing clinical trials may, depending on the data, also result in the delay, suspension or termination of one or more of our clinical trials, which would also delay or prevent the initiation of our other planned clinical trials. If we experience termination of, or delays in the completion of, any clinical trial of our therapeutic candidates, the commercial prospects for our therapeutic candidates will be harmed, and our ability to generate revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence therapeutic sales and generate revenue. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our therapeutic candidates.

***To the extent our Biovance and Interfyl products do not qualify for regulation as HCT/P solely under Section 361 of the PHSA, this could result in removal of these products from the market.***

In November 2017, the FDA released a guidance document entitled "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use — Guidance for Industry and Food and Drug Administration Staff", which it revised and reissued in July 2020. The document confirmed the FDA's stance that sheet forms of amniotic tissue are appropriately regulated as solely Section 361 HCT/Ps when manufactured in accordance with 21 CFR Part 1271 and intended for use as a barrier or covering. However, wound healing is not a homologous use of amniotic tissue, and to the extent we make claims for Biovance and Interfyl, two products in our degenerative disease business, that extend beyond homologous use, we may be subject to FDA enforcement. The Guidance stated that the FDA intended to exercise enforcement discretion under limited conditions with respect to the IND application and pre-market approval requirements for certain HCT/Ps for a period that expired on May 31, 2021. The FDA's approach is risk-based, and the Guidance clarified that high-risk products and uses could be subject to immediate enforcement action. New York has interpreted the Guidance such that it has restricted the marketing of such products without BLA approval, notwithstanding the current exception in the Guidance, and other states may make similar determination, which would limit the market for such products until a BLA is approved.

Amniotic tissue is generally eligible for regulation solely as a HCT/P under Section 361 of the PHSA depending on whether the specific product at issue and the claims made for it are consistent with the applicable FDA criteria for minimal manipulation and homologous use. HCT/Ps that do not meet these minimal manipulation and homologous use criteria are subject to more extensive regulation as drugs, medical devices, biological products, or combination products. Such HCT/Ps must comply with both the FDA's requirements for HCT/Ps and the requirements applicable to biologics, devices or drugs, including pre-market clearance or approval from the FDA.

We may need to either modify our claims or cease selling our Biovance and Interfyl products until the FDA approves a BLA, and then we will only be able to market such products for indications that have been approved in a BLA. The loss of our ability to market and sell these products would have an adverse impact on our revenues, business, financial condition and results of operations. In addition, we expect the cost to manufacture our products will increase due to the costs to comply with the requirements that apply to Section 351



biological products, such as current cGMP and ongoing product testing costs. Increased costs relating to regulatory compliance could have an adverse impact on our business, financial condition and results of operations.

In addition, the FDA might, at some future point, modify its position on which current or future products qualify as Section 361 HCT/Ps. Any regulatory changes could have adverse consequences for us and make it more difficult or expensive for us to conduct our business by requiring pre-market clearance or approval and compliance with additional post-market regulatory requirements with respect to those products. It is also possible that the FDA could require us to recall our Biovance and Interfyl products.

***We expect the therapeutic candidates we develop will be regulated as biological products, or biologics, and they may be subject to competition sooner than anticipated.***

The BPCIA, was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the therapeutic candidates we develop that are approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject therapeutic candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***The regulatory landscape that will govern our therapeutic candidates is uncertain; regulations relating to more established cellular therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our therapeutic candidates or unexpected costs in obtaining regulatory approval.***

Because we are developing novel cellular therapeutic candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear. Regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. Although the FDA decides whether individual therapy protocols may proceed, review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which a clinical trial will be conducted. In addition, adverse developments in clinical trials of gene or cell therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our therapeutic candidates. Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our therapeutic candidates, further complicating the regulatory landscape.

The various committees and advisory groups involved in regulatory review, and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our therapeutic candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our placental-derived cell therapeutic candidates is new, we may face even more cumbersome and complex regulations than those for more traditional pharmaceutical or biological products. Furthermore, even if our therapeutic candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential therapeutic to market could decrease our ability to generate sufficient revenue to maintain our business.

***The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our cell therapeutic candidates.***

If we complete our planned and Phase 1 and Phase 1/2a clinical trials and obtain positive data, we expect to advance to potential registration trials. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. If the results are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for the relevant therapeutic candidate. However, we do not have any agreement or



guidance from the FDA that its regulatory development plans will be sufficient for submission of a BLA. For example, the FDA may require that we conduct a comparative trial against an approved therapy including potentially an approved autologous cell therapy, which would significantly delay our development timelines and require substantially more resources. In addition, the FDA may only allow us to evaluate patients that have failed or who are ineligible for autologous therapy, which are extremely difficult patients to treat and patients with advanced and aggressive cancer, and our therapeutic candidates may fail to improve outcomes for such patients.

If the FDA grants us accelerated approval based on Phase 1/2a clinical trial results, if and when such trials occur, as a condition for accelerated approval, the FDA may require us 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. However, the FDA may ultimately require a Phase 3 clinical trial prior to approval, particularly because our therapeutic candidates represent a novel treatment methods. In addition, the standard of care may change with the approval of new therapeutics in the same indications that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to evaluate our therapeutic candidate relative to newly approved therapeutics.

Our clinical trial results may also not support approval. In addition, our therapeutic 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;
- We may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our therapeutic candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations;
- We may be unable to demonstrate that our therapeutic candidates' clinical and other benefits 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 therapeutic 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 will review our manufacturing process and inspect our commercial manufacturing facility and may not approve our manufacturing process or facility; 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.

***We plan to seek orphan drug designation for some or all of our therapeutic candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, 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. 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. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but if a product that has orphan drug designation subsequently receives the first FDA approval of that particular product 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 (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances. See the section entitled “*Business — Government Regulation and Product Approval*” for more information regarding orphan drug designation. Even though in April 2021, the FDA granted orphan drug designation to our non-genetically modified cryopreserved human placental hematopoietic stem cell-derived NK cell therapy, CYNK-001, for the treatment of patients with malignant gliomas, and, in February 2022, the FDA granted orphan drug designation to our investigational natural killer cell therapy, CYNK-101, for the treatment of gastric/gastroesophageal junction cancer, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our therapeutic or if a subsequent applicant demonstrates clinical superiority over our product.

We plan to seek orphan drug designation for some or all of our therapeutic candidates in specific orphan indications in which there is a medically plausible basis for the use of these therapeutics. Even if we obtain orphan drug designation, 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 we are unable to assure sufficient quantities of the therapeutic to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our therapeutics, if approved.

***We may not elect or be able to take advantage of any expedited development or regulatory review and approval processes available to therapeutic candidates granted breakthrough therapy or fast track designation by the FDA.***

We intend to evaluate and continue ongoing discussions with the FDA on regulatory strategies that could enable us to take advantage of expedited development pathways for certain of our therapeutic candidates, although we cannot be certain that our therapeutic candidates will qualify for any expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant qualifying designations. Potential expedited development pathways that we could pursue include breakthrough therapy and fast track designation.

Breakthrough therapy designation is intended to expedite the development and review of therapeutic candidates that are designed to treat serious or life-threatening diseases when “preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.” The designation of a therapeutic candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the therapeutic candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review. Fast track designation is designed for therapeutic candidates intended for the treatment of a serious or life-threatening disease or condition, where nonclinical or clinical data demonstrate the potential to address an unmet medical need for this disease or condition.

Although we have received fast track designation for certain of our cell therapy candidates, we may elect not to pursue either of breakthrough therapy or fast track designation for our other therapeutic candidates, and the FDA has broad discretion whether or not to grant these designations.

Accordingly, even if we believe that a particular therapeutic candidate is eligible for breakthrough therapy or fast track designation, we cannot assure you that the FDA would decide to grant such designation. Breakthrough therapy designation and fast track designation do not change the standards for product approval, and there is no assurance that such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the breakthrough therapy designation or fast track designation. Thus, even if we do receive breakthrough therapy or fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw breakthrough therapy or fast track designation if it believes that the product no longer meets the qualifying criteria. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways.

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

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

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of therapeutic candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for it 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 receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our therapeutic candidates will be harmed.

***Even if we receive regulatory approval of our therapeutic 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 therapeutic candidates.***

Any regulatory approvals that we receive for our therapeutic candidates will require surveillance to monitor the safety and efficacy of the therapeutic candidate. The FDA may also require a REMS in order to approve our therapeutic candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our therapeutic candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and current GCPs for any clinical trials that we conduct post-approval, and compliance with applicable product tracking and tracing requirements. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work with must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, 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 and social media. 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. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

Later discovery of previously unknown problems with our therapeutic candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers, or our manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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 therapeutic candidates. 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. 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.

***Negative public opinion and increased regulatory scrutiny of genetic research and therapies involving gene editing or modified cells may damage public perception of our therapeutic candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our therapeutic candidates.***

The gene-editing technologies that we use are novel. Public perception may be influenced by claims that gene editing is unsafe, and products incorporating gene editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our therapeutic candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of gene editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to utilize our treatments or participate in clinical trials for our therapeutic candidates. In addition, given the novel nature of gene-editing and cell therapy technologies, governments may place import, export or other restrictions in order to retain control or limit the use of the technologies.

Increased negative public opinion or more restrictive government regulations either in the United States or internationally, would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our therapeutic candidates or demand for such therapeutic candidates.

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

The use of engineered placental-derived cells as a potential treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. We may not be able to educate these persons on the benefits of using our therapeutic candidates for many reasons. For example, certain of the therapeutic candidates that we will be developing target a cell surface marker that may be present on cancer cells as well as non-cancerous cells. It is possible that our therapeutic candidates may kill these non-cancerous cells, which may result in unacceptable side effects, including death. Additional factors will influence whether our therapeutic candidates are accepted in the market, including:

- the clinical indications for which our therapeutic candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our therapeutic candidates as a safe and effective treatment;
- the potential and perceived advantages of our therapeutic 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 timing of market introduction of our therapeutic candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our therapeutic candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our cell therapies 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 therapeutics, are more cost effective or render our therapeutics obsolete.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our therapeutic candidates, which could make it difficult for us to sell our cell therapies, if approved, profitably.***

Successful sales of our therapeutic candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any therapeutic candidates for which we obtain regulatory approval. In addition, because our therapeutic candidates represent new approaches to the treatment of cancer, infectious and degenerative diseases, we cannot accurately estimate the potential revenue from our therapeutic candidates. For more information on coverage and reimbursement requirements see the section entitled “*Business — Government Regulation and Product Approval – Coverage, Pricing and Reimbursement.*”

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. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor’s determination that use of a therapeutic is:



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

Obtaining coverage and reimbursement of a therapeutic from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our therapeutics. Even if we obtain coverage for a given therapeutic, if the resulting reimbursement rates are insufficient, hospitals may not approve our therapeutic for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our therapeutic candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our therapeutic candidates. Separate reimbursement for the therapeutic itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our therapeutic is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors and reduce the willingness of physicians to use our therapeutic candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our therapeutic candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our therapeutic candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, 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 therapeutic candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular therapeutic candidate to currently available therapies. Other EU member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any therapeutic candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more therapeutics for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

***The advancement of healthcare reform may negatively impact our ability to sell our therapeutic candidates, if approved, profitably.***

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our therapeutic candidates, if approved, profitably. Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. See the section entitled "Business — Government Regulation and Product Approval – *Healthcare Reform*" for a discussion of these laws and regulations. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our therapeutics. Such reforms could have an adverse effect on anticipated revenue from therapeutic candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop therapeutic candidates.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance



programs, and reform government program reimbursement methodologies for drugs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We cannot predict the initiatives that may be adopted in the future. Additionally, the continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our therapeutic candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our therapeutics;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

### **Risks Related to Our Intellectual Property**

*If our efforts to protect the proprietary nature of the intellectual property related to our technologies is not adequate, we may not be able to compete effectively in our market.*

As is the case with other biopharmaceutical companies, our success depends in large part on our ability to obtain and maintain protection of intellectual property. We rely upon a combination of patents, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We have filed additional patent applications, and we anticipate additional patent applications will be filed in the future, both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when 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 or not others will 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, which may be costly whether we win or lose.

Obtaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we may fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications licensed from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

We cannot be certain that the claims in our pending patent applications will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our therapeutic 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 patentability, validity, enforceability or scope thereof, which may result in such patents being canceled, 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 therapeutic candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our therapeutic candidates. Further, if we encounter delays in our clinical trials, the

period of time during which we could market our therapeutic candidates under patent protection would be reduced. Further, changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

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.

***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, 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. We take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, corporate partners and, when needed, advisers. Trade secrets, however, may be difficult to protect.

Monitoring unauthorized disclosure and detection of unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable.

Although we require all of our employees to assign their inventions to us, and requires all of our employees and key consultants who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not 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 confidential information or intellectual property to 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.

***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. Although we try to ensure that our employees, consultants, advisors and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary or confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential technologies and solutions, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management team and employees.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Any of the foregoing could harm our business, financial condition, results of operations and prospects.

***Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts and our ability to commercialize our therapeutic candidates.***

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

Third parties may assert that we infringe their patents or are otherwise employing their proprietary technology without authorization and may sue. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our therapeutic candidates may be alleged to infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our therapeutic candidates, constructs or molecules used in or formed during the manufacturing process, or any final therapeutic itself, the holders of any such patents may be able to block our ability to commercialize the therapeutic candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held not infringed, unpatentable, invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the therapeutic candidate unless we obtain a license or until such patent expires or is finally determined to be held not infringed, unpatentable, invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our therapeutic candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our therapeutic candidates. 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 and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our therapeutic candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our therapeutic candidates, which could harm our business significantly.

***We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.***

Presently, we have rights to the intellectual property, through licenses from third parties and under patent applications that we own or will own, that we believe will facilitate the development of our therapeutic candidates. In the future, we may identify third party intellectual property and technology that we may need to acquire or license in order to engage in our business, including to develop or commercialize new technologies or services, and the growth of our business may depend in part on our ability to acquire, in-license or use this technology.

We may be unable to acquire or in-license any third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, we may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights to the extent we are unable to maintain our license with any such third-party licensors.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our therapeutic candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If such licenses are available, we may be required to pay the licensor in return for the use of such licensor's technology, lump-sum payments, payments based on certain milestones such as sales volumes, or royalties based on sales. In addition, our licenses may also place restrictions on our future business opportunities.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize technology covered by these license agreements. If these licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market products that use technologies identical to those licensed to us. This could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. Additionally, termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do

so, may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more technologies that rely on such agreements.

In addition to the above risks, intellectual property rights that may be licensed now or in the future could include sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize therapeutic candidates may be materially harmed.

Further, we may not have the right to control the prosecution, maintenance and enforcement of all of our licensed and sublicensed intellectual property, and even when we do have such rights, we may require the cooperation of our licensors and upstream licensors, which may not be forthcoming. Our business could be adversely affected if we or our licensors are unable to prosecute, maintain and enforce licensed and sublicensed intellectual property effectively.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents and patent applications in-licensed. If other third parties have ownership rights to patents or patent applications in-licensed by us, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our business, financial condition, results of operations and prospects could be materially and adversely affected if we are unable to enter into necessary agreements on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the acquired or licensed patents or other rights are found to be invalid or unenforceable. Moreover, we could encounter delays in the introduction of services while we attempt to develop alternatives. Further, defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, which could harm our business, financial condition, or results of operations and prospects.

***We may be involved in lawsuits or other legal proceedings 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 or misappropriate or otherwise violate our intellectual property rights or the intellectual property rights of our licensors. In the future, we or our licensors may initiate legal proceedings to enforce or defend our intellectual property rights or the intellectual property rights of our licensors, to protect our trade secrets or the trade secrets of our licensors, or to determine the validity or scope of intellectual property rights we own or control.

To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Third parties may also initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. In an infringement proceeding, a court may decide that one or more of our patents are not valid or are 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 one or more of our pending 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. Additionally, many of our adversaries or adversaries of our licensors in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Third-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us or our licensors, may challenge or be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to us or our licensor's patents or patent applications. An unfavorable outcome could leave our technology or therapeutic candidates without patent protection, allow third parties to commercialize our technology or therapeutic candidates and compete directly with us, without payment to us, or could require us or our licensors to cease using the related technology or to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our therapeutic candidates without infringing third-party patent rights.

Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or other legal 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. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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 our common stock. If the breadth or strength of protection provided by us or our licensor's patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize therapeutic candidates. Moreover, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue clinical trials, continue research programs, license necessary technology from third parties, or enter into collaborations.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO, and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***The lives of our patents may not be sufficient to effectively protect our products and business.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our therapeutic candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If our technologies require extended development and/or regulatory review, patents protecting our technologies might expire before or shortly after we are able to successfully commercialize them. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

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

We or our licensors 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 therapeutic candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

We may not be able to protect our intellectual property rights outside the United States. Filing, prosecuting and defending patents on therapeutic candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Whether filed in the United States or abroad, our patents and patent applications may be challenged or may fail to result in issued patents. 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 its 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 is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. Furthermore, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the misappropriation or other violations of our intellectual property rights including infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, or that are initiated against us, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technologies and the enforcement of intellectual property. 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.

***Changes in patent law, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries or regions may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third party patents. We may not develop additional proprietary technologies that are patentable.

Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On or after March 16, 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted on September 16, 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us, could therefore be awarded a patent covering an invention of ours, even if we have made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Because patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our technology or (ii) invent any of the inventions claimed in us or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent position of companies in the biotechnology field is particularly uncertain. Various courts, including the United States Supreme Court have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to biotechnology. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature or abstract idea is uncertain, and it is possible that certain aspects of our technology could be considered natural laws. Accordingly, the evolving case law in the United States, and abroad, may adversely affect us and our licensor's ability to obtain new patents or to enforce existing patents and may facilitate third party challenges to any owned or licensed patents.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain any competitive advantage. For example:

- others may be able to make products that are similar to any therapeutic candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we license or may own in the future;
- we, or our, current or future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we license or may own in the future;
- we, or our, current or future collaborators, might not have been the first to file patent applications covering certain of our intellectual property or our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive therapeutics for sale in our major commercial markets;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable therapeutic candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or therapeutic candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our therapeutic candidates on a substantial scale, if approved, before the relevant patents that we own or licenses expire;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our therapeutic candidates;
- we may not develop additional proprietary technologies that are patentable;
- the patents or intellectual property rights of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

**Risks Related to Ownership of Our Class A Common Stock**

***There may not be an active trading market for our securities, which may make it difficult to sell shares of Class A common stock.***

It is possible that an active trading market for our securities will not develop or, if developed, that any market will not be sustained. This would make it difficult for us to sell our securities at an attractive price or at all.

***The market price of our securities may be volatile, which could cause the value of an investment to decline.***

The price of our securities may fluctuate significantly due to general market and economic conditions. An active trading market for our securities may not develop or, if developed, it may not be sustained. In addition, fluctuations in the price of our securities could contribute to the loss of all or part of the investment in us. Even if an active market for our securities develops and continues, the trading price of our securities could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on your investment in our securities and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- the realization of any of the risk factors presented in this annual report;
- actual or anticipated fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- changes in the market's expectations about our operating results;
- our operating results failing to meet the expectation of securities analysts of investors in a particular period;
- operating and share price performance of other companies that investors deem comparable to us;
- the volume of shares of Class A common stock available for public sale;
- future issuances, sales, resales or repurchases or anticipated issuances, sales, resales or repurchases of our securities;
- the commencement, enrollment or results of our ongoing and planned clinical trials of our therapeutic candidates or any future clinical trials we may conduct, or changes in the development status of our therapeutic candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse results or delays in clinical trials;
- any delay in our regulatory filings for our therapeutic candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- our failure to commercialize our therapeutic candidates;
- adverse regulatory decisions, including failure to receive regulatory approval of our therapeutic candidates;
- changes in laws or regulations applicable to our therapeutic candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning manufacturers or suppliers;
- our inability to manufacture or obtain adequate supply for any approved therapeutic or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to cellular therapies;
- introduction of new therapeutics or services offered by our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage growth;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or cellular therapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the structure of healthcare payment systems;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- speculation in the press or investment community;
- sales of Class A common stock by us or our stockholders in the future;

- the trading volume of our Class A common stock;
- changes in accounting practices;
- the ineffectiveness of our internal control over financial reporting;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain or maintain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions, including health pandemics, such as COVID-19; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Class A common stock, regardless of its actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any cash dividends in the foreseeable future. As a result, you may only receive a return on your investment in our Class A common stock if the trading price of your shares increases.

***Our Class A common stock may be delisted from the Nasdaq and begin trading in the over-the-counter markets if we are not successful in regaining compliance with the Nasdaq's continued listing standards, which may negatively impact the price of our common stock and our ability to access the capital markets.***

On March 14, 2023, we received notice from the Listing Qualifications department of the Nasdaq Stock Market LLC, or Nasdaq, notifying us that we no longer comply with the minimum bid price requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5450(a)(1) because the closing bid price for our Class A common stock has fallen below \$1.00 per share for the last 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until September 11, 2023, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our Class A common stock must meet or exceed \$1.00 per share for a minimum of 10 consecutive business days prior to September 11, 2023. If we do not regain compliance by September 11, 2023, we may be eligible for an additional 180-day grace period if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement. We intend to actively monitor the closing bid price of our Class A common stock and will evaluate available options to regain compliance with the minimum bid requirement. However, there can be no assurance that we will regain compliance with the minimum bid requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance, or maintain compliance with the other Nasdaq listing requirements.

If we are not successful, or choose not to implement a reverse stock split, we anticipate that our securities would begin trading on the over-the-counter market. Delisting from Nasdaq and trading on the over-the-counter market could adversely affect the liquidity of our securities. Securities traded on the over-the-counter market generally have limited trading volume and exhibit a wider spread between the bid/ask quotation, as compared to securities listed on a national securities exchange. Consequently, you may not be able to liquidate your investment in the event of an emergency or for any other reason.

If Nasdaq delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences including:

- limited availability of market quotations for our securities;
- a determination that the Class A common stock is a "penny stock" which will require brokers trading in the Class A common stock to adhere to more stringent rules;
- possibly resulting in a reduced level of trading activity in the secondary trading market for shares of the Class A common stock;
- a limited amount of analyst coverage; and

- a decreased ability to issue additional securities or obtain additional financing in the future.

***Future sales and issuances of our Class A common stock or rights to purchase common stock, including pursuant to our equity plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We may also sell our common stock as part of entering into strategic alliances, creating joint ventures or collaborations or entering into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our Class A common stock.

***Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our Class A common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.***

Our second amended and restated certificate of incorporation and our amended and restated bylaws adopted in connection with the completion of the Business Combination contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of our board of directors will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of our board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of our board of directors to issue preferred stock on terms determined by the directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our charter and bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our Class A common stock to decline.

***Our charter provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.***

Our charter provides that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;



- any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our charter or the bylaws;
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our charter or bylaws;
- any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our directors, officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our charter provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our charter. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with our company or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

## **General Risk Factors**

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.***

The global credit and financial markets have experienced extreme volatility and disruptions in the past, most recently including as a result of the ongoing COVID-19 pandemic, and more recently, the failure of Silicon Valley Bank. These disruptions can result in severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require it to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the equity ownership of certain stockholders over a rolling three-year period), our ability to use our pre-change federal net operating loss, or NOL, carryforwards and other pre-change tax attributes to offset our post-change income and taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2022, we had approximately \$84.6 million of U.S. federal and \$18.2 million state NOL carryforwards, and these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our profitability. We anticipate incurring significant additional net losses for the foreseeable future, and our ability to utilize NOL carryforwards associated with any such losses

to offset future taxable income may be limited to the extent we incur future ownership changes. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

***Changes in tax law could adversely affect our business and financial condition.***

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our securities. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. For example, the IRA includes a 15% corporate alternative minimum tax and a 1% excise tax on share repurchases. We urge investors to consult with their legal and tax advisers regarding the implications of changes in tax laws on an investment in our securities.

***Fluctuations in the cost and availability of raw materials, equipment, labor, and transportation could cause manufacturing delays or increase our costs.***

The price and availability of key components used to manufacture our products has been increasing and may continue to fluctuate significantly. In addition, the cost of labor internally or at our third-party manufacturers could increase significantly due to regulation or inflationary pressures. Additionally, the cost of logistics and transportation fluctuates in large part due to the price of oil, and availability can be limited due to political and economic issues. Any fluctuations in the cost and availability of any of our raw materials, packaging, or other sourcing or transportation costs could harm our gross margins. If we are unable to successfully mitigate a significant portion of these product cost increases or fluctuations, our results of operations could be harmed.

## **Item 1B. Unresolved Staff Comments.**

None.

## **Item 2. Properties.**

We occupy approximately 150,000 square feet of office, laboratory and manufacturing space in Florham Park, New Jersey under a lease expiring in 2036, which we use as our principal place of business. We believe that our existing facilities will be sufficient for our needs for the foreseeable future.

## **Item 3. Legal Proceedings.**

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact because of defense and settlement costs, diversion of management resources and other factors.

On June 9, 2021, John Schlechtweg, a former employee, filed a complaint against us in the United States District Court for the District of Connecticut alleging breach of verbal contract and, alternatively, unjust enrichment. The complaint specifically alleges that we have refused to pay Mr. Schlechtweg additional compensation relating to his involvement in the sale of certain assets to Sanuwave. Following preliminary motion practice, the matter was transferred to the United States District Court for the District of New Jersey. The breach of contract claim was subsequently dismissed on motion to dismiss on the pleadings, with the sole remaining claim for unjust enrichment. The are parties currently engaged in discovery. We believe the remaining claim asserted in the action is without merit and intend to vigorously defend against it, but there can be no assurance as to the outcome of the litigation.

On February 4, 2021, a putative class action lawsuit was filed in the Supreme Court of the State of New York by a purported stockholder in connection with the Business Combination: Spero v. GX Acquisition Corp., et al., Index No. 650812/2021 (N.Y. Sup Ct. Feb 04, 2021). On February 26, 2021, the same purported stockholder filed an amended complaint in the lawsuit removing the class action allegations and certain of the other allegations, or the Spero Complaint. On February 8, 2021, a complaint was filed with the Supreme Court of the State of New York by a purported stockholder in connection with the Business Combination: Rogalla v. GX Acquisition Corp., et al., Index No. 650877/2021 (N.Y. Sup Ct. Feb 08, 2021), or the Rogalla Complaint, and together with the Spero Complaint, the Complaints). The Complaints name our Company and members of our board of directors (prior to the Business Combination), or GX and the GX Board, respectively, as defendants. Additionally, the Rogalla Complaint named First Merger Sub, Second Merger Sub and Celularity as defendants. The Rogalla Complaint alleged breach of fiduciary duty claims against the GX Board in connection with the Business Combination and aiding and abetting the GX Board's breaches of fiduciary duties claims against GX, First Merger Sub, Second Merger Sub and Celularity. These claims are based on allegations that the prospectus in connection with the Business Combination was materially misleading and/or omitted material information concerning the Business Combination. The Spero Complaint alleged breach of fiduciary duty claims against the GX Board in connection with the Business Combination and aiding and abetting the GX Boards' breaches of fiduciary duties claims against GX. These claims were based on the sales process and valuation of Celularity, as well as allegations that the S-4 Registration Statement related to the Business Combination was materially misleading and/or omitted material information concerning the Business Combination. The Complaints generally requested injunctive relief or rescission, unspecified damages and awards of attorneys' and experts' fees, among other remedies. On April 29, 2021, the plaintiff that filed the Spero Complaint voluntarily discontinued that action. On July 20, 2021, the plaintiff that filed the Rogalla Complaint voluntarily discontinued that action.

The GX Board also received four demands from putative stockholders of GX dated February 18, 2021, March 2, 2021, March 19, 2021 and March 24, 2021, together, the Demands, alleging that GX and the GX Board have breached their fiduciary duties and violated federal securities laws because the prospectus allegedly was materially misleading and/or omitted material information concerning the Business Combination. The Demands sought the issuance of corrective disclosures in an amendment or supplement to the prospectus. While GX believed that the above allegations were all without merit, on March 29, 2021, GX filed an amended Form S-4 with the SEC that contained certain additional information that mooted the disclosure claims asserted in the Complaints and the Demands, the Supplemental Disclosures. In connection with the filing of the Supplemental Disclosures, counsel for the plaintiffs in the Complaint and the Demands agreed that, in light of the mootness of their claims, they would stand down and not take any further action with respect to the Business Combination or the prospectus, and subsequently entered into a confidential agreement with GX to resolve any and all claims that were or could have been raised in the Complaints and the Demands.

We received a Civil Investigative Demand, or the Demand, under the False Claims Act, 31 U.S.C. § 3729, dated August 14, 2022, from the U.S. Attorney's Office for the Eastern District of Pennsylvania. The Demand requests documents and information relating to claims submitted to Medicare, Medicaid, or other federal insurers for services or procedures involving injectable human tissue therapy products derived from amniotic fluid or birth tissue and includes Interfyl. We are cooperating with the request and are engaged in an

ongoing dialogue with the Assistant U.S. Attorneys handling the Demand. The matter is still in preliminary stages and there is uncertainty as to whether the Demand will result in any liability.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## **PART II**

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

#### **Market Information**

Shares of our Class A common stock have traded on the Nasdaq Capital Market under the ticker symbol “CELU”. Our ticker symbol for our warrants exercisable for one share of Class A common stock at an exercise price of \$11.50 per share is “CELUW”.

#### **Holders**

As of March 31, 2023, there were approximately 111 stockholders of record of our Class A common stock and 6 holders of our warrants.

#### **Dividends**

We have never declared or paid any dividends on our capital or common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors.

#### **Securities Authorized for Issuance under Equity Compensation Plans**

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this annual report

#### **Recent Sales of Unregistered Securities**

None.

#### **Issuer Purchases of Equity Securities**

None.

#### **Item 6. [Reserved]**



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

*The following discussion contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. See "Special Note Regarding Forward-Looking Statements." Such forward-looking statements, which represent our intent, belief, or current expectations, involve risks and uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terms such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions. Factors that could cause or contribute to differences in results include, but are not limited to, those set forth under Item 1.B. "Risk Factors" and elsewhere in this annual report. Except as required by law, we undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.*

### Overview

We are a biotechnology company leading the next evolution in cellular medicine by developing off-the-shelf placental-derived allogeneic cell therapies for the treatment of cancer and immune and infectious diseases. We are developing a pipeline of off-the-shelf placental-derived allogeneic cell therapy product candidates including T cells engineered with a chimeric antigen receptor, or CAR, natural killer, or NK, cells, mesenchymal-like adherent stromal cells, or MLASCs and exosomes. These therapeutic candidates target indications across cancer, infectious and degenerative diseases. We believe that by harnessing the placenta's unique biology and ready availability, we will be able to develop therapeutic solutions that address a significant unmet global need for effective, accessible and affordable therapeutics. We also actively develop and market biomaterial products derived from the placenta. Prior to 2023, we marketed those products domestically primarily serving the orthopedic and wound care markets. We now intend to market placental biomaterials outside of the United States with an initial focus on markets in the Middle East and North Africa. Our biomaterials business today is comprised primarily of the sale of our Biovance and Interfyl products, directly or through our distribution network. Biovance is decellularized, dehydrated human amniotic membrane derived from the placenta of a healthy, full-term pregnancy. It is an intact, natural extracellular matrix that provides a foundation for the wound regeneration process and acts as a scaffold for restoration of functional tissue. Interfyl is human connective tissue matrix derived from the placenta of a healthy, full-term pregnancy. It is used by a variety of medical specialists to fill soft tissue deficits resulting from wounds, trauma, or surgery. We are developing new placental biomaterial products to deepen the commercial pipeline beyond Biovance and Interfyl. We also plan to leverage our core expertise in cellular therapeutic development and manufacturing to generate revenues by providing contract manufacturing and development services to third parties. The initial focus of this new service offering will be to assist development stage cell therapy companies with the development and manufacturing of their therapeutic candidates for clinical trials. In January 2023, we announced reprioritization of efforts which resulted in a reduction of approximately one-third of our workforce as of March 2023.

### Recent Developments

#### Private Placement

On March 20, 2023, we entered into a securities purchase agreement with two accredited investors, including our Chairman and Chief Executive Officer, Dr. Robert Hariri, providing for the private placement of (i) 9,381,841 shares of our Class A common stock, and (ii) accompanying warrants to purchase up to 9,381,841 shares of Class A common stock, or the PIPE Warrants, for \$0.8343 per share and \$0.125 per accompanying PIPE Warrant, for an aggregate purchase price of approximately \$9.0 million (of which Dr. Hariri subscribed for \$2.0 million). The closing of the private placement occurred on March 27, 2023 and was subject to the satisfaction of customary closing conditions.

Each PIPE Warrant has an exercise price of \$3.00 per share, is immediately exercisable, will expire on March 27, 2028 (five years from the date of issuance), and is subject to customary adjustments for certain transactions affecting our capitalization. The PIPE Warrants may not be exercised if the aggregate number of shares of Class A common stock beneficially owned by the holder thereof (together with its affiliates) would exceed the specified percentage cap provided therein (which may be adjusted upon 61 days advance notice) immediately after exercise thereof.

We also entered into a registration rights agreement with the purchasers whereby we agreed to register the resale of the shares of Class A common stock and the shares of Class A common stock issuable upon exercise of the PIPE Warrants as well as the shares issued as payment pursuant to the binding term sheet for a sublicense (described below). We will be required to prepare and file a registration statement with the Securities and Exchange Commission, or SEC, within 30 days of the filing of this annual report, and to use commercially reasonable efforts to have the registration statement declared effective within 45 days if there is no review by the SEC, and within 90 days in the event of such review, and in any event, no later than June 30, 2023.

The securities were issued pursuant to an exemption from registration provided for under Section 4(a)(2) of the Securities Act of 1933, as amended, or the Act, and Regulation D promulgated thereunder. We relied on this exemption from registration based in part on representations made by the purchasers.

#### Senior Secured Bridge Loan

On March 17, 2023, we entered into a Loan Agreement with C.V. Starr & Co. Inc., one of our significant stockholders, or Starr, providing for a loan in the aggregate principal amount of \$5.0 million net of an original issue discount of \$100,000, which bears interest at a rate of 12.0% per year, with the first year of interest being paid in kind on the last day of each month, and matures March 17, 2025, or the Loan, and warrants to acquire up to an aggregate 750,000 shares of our Class A common stock, or the Starr Warrant, at a purchase price of \$0.125 per whole share underlying the Starr Warrant (or \$93,750). The Starr Warrant has a 5-year term and an exercise price of \$0.71 per share. We closed the Loan and the sale and purchase of the Starr Warrant on March 17, 2023.

Pursuant to the terms of the Loan, we agreed to customary negative covenants restricting our ability to repay indebtedness, pay dividends to stockholders, repay or incur other indebtedness other than as permitted, grant or suffer to exist a security interest in any our assets, other than as permitted, or hold cash and cash equivalents less than \$3.0 million for more than five consecutive business days. In addition to the negative covenants in the Loan, the Loan include customary events of default. Pursuant to the terms of the Loan, we granted Starr a senior security interest in all of its assets.

#### *Binding Term Sheet for Sublicense Agreement*

Concurrent with the entry into the securities purchase agreement for the private placement described above; we executed a binding term sheet to negotiate and enter into a sublicense of certain assets from an affiliate of the accredited investor party to the private placement transaction. Pursuant to the binding term sheet, we paid the sublicensor \$3.0 million in cash and issued \$1.0 million of shares of our Class A common stock (1,694,915 shares based on the closing price on March 17, 2023).

#### ***Going Concern***

In accordance with Accounting Standards Update ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), or ASU 205-40, we evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

As an emerging clinical-stage biotechnology company, we are subject to certain inherent risks and uncertainties associated with the development of an enterprise. In this regard, since our inception, substantially all of management's efforts have been devoted to making investments in research and development including basic scientific research into placentally-derived allogeneic cells, pre-clinical studies to support our current and future clinical programs in cellular therapeutics, and clinical development of our cell programs as well as facilities and selling, general and administrative expenses that support our core business operations (collectively the "investments"), all at the expense of our short-term profitability. We have historically funded these investments through limited revenues generated from our biobanking and degenerative disease businesses and issuances of equity and debt securities to public and private investors (these issuances are collectively referred to as "outside capital"). Notwithstanding these efforts, management can provide no assurance that our research and development and commercialization efforts will be successfully completed, or that adequate protection of our intellectual property will be adequately maintained. Even if these efforts are successful, it is uncertain when, if ever, we will generate significant sales or operate in a profitable manner to sustain our operations without needing to continue to rely on outside capital. Continued decline in our share price could result in impairment of goodwill or long-lived assets in a future period.

As of the date the accompanying consolidated financial statements were issued (the "issuance date"), management evaluated the significance of the following adverse conditions and events in accordance with ASU 205-40:

- Since inception, we have incurred significant operating losses and used net cash outflows from operations. For the year ended December 31, 2022, we incurred a net operating loss of \$25.6 million and used net cash in operations of \$137.9 million. As of December 31, 2022, we had an accumulated deficit of \$645.5 million. We expect to continue to incur significant operating losses and use net cash in operations for the foreseeable future.
- As of the issuance date, we had approximately \$8.6 million of unrestricted cash and cash equivalents available to fund our operations and no available additional sources of outside capital to sustain our operations for a period of 12 months beyond the issuance date.
- We expect to incur substantial expenditures to fund our investments for the foreseeable future. In order to fund these investments, we will need to secure additional sources of outside capital. While we are actively seeking to secure additional outside capital (and have historically been able to successfully secure such capital), as of the issuance date, no additional outside capital has been secured or was deemed probable of being secured. In addition, management can provide no assurance that we will be able to secure additional outside capital in the future or on terms that are acceptable to us. Absent an ability to secure additional outside capital in the very near term, we will be unable to meet its obligations as they become due over the next 12 months beyond the issuance date.
- We had approximately \$37.0 million of borrowings outstanding under a financing arrangement referred to as the PPA with a private investor, Yorkville, as of December 31, 2022. These borrowings are scheduled to mature in September 2023 absent Yorkville's election to convert some or all of the borrowings into shares of our common stock. On February 22 2023,

Yorkville provided notice to us that a “triggering event” had occurred, as provided for under the terms of the PPA. As a result of this triggering event, we are now required to make repayments of \$6.0 million per month plus a payment premium of 5% of the principal amount being paid and all outstanding accrued and unpaid interest (collectively the “repayment amount”). On March 24, 2023, we paid approximately \$2.0 million of the repayment amount owed to Yorkville and are currently seeking to secure a waiver from Yorkville to, among other things, defer the remaining repayment amount owed of approximately \$11.0 million. However, a waiver has not been secured as of the issuance date. If we fail to secure a waiver from Yorkville and fail to pay the remaining repayment amount currently due, Yorkville could deem such non-payment an event of default under the PPA. If Yorkville deems such non-payment an event of default, Yorkville may, at its discretion, exercise its rights and remedies as provided in the PPA which may include, among others, accelerating the repayment of the total principal due under the PPA (\$37.0 million as of December 31, 2022 or approximately \$32.6 million as of issuance date), plus accrued and unpaid interest and the 5% premium, and/or force us to seek protection under the provisions of the U.S. Bankruptcy Code.

- On March 14, 2023, we received a notice from the Nasdaq notifying us that we no longer comply with the minimum bid price requirement for continued listing on the Nasdaq Capital Market because the closing bid price for our Class A common stock has fallen below \$1.00 per share for the last 30 consecutive business days. We have a period of 180 calendar days, or until September 11, 2023, to regain compliance with the minimum bid price requirement. We intend to actively monitor the closing bid price of our Class A common stock and will evaluate available options to regain compliance with the minimum bid requirement. However, management can provide no assurance that we will be able to regain compliance with the minimum bid requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance, or maintain compliance with the other Nasdaq listing requirements. In the event we are unable to regain or maintain compliance with the Nasdaq listing requirements, the liquidity of our publicly traded securities will be adversely affected and our ability to secure additional outside capital through public markets will be adversely affected.
- In the event we are unable to secure additional outside capital to fund our obligations when they become due over the next 12 months beyond the issuance date, which includes the funds needed to repay the outstanding principal on the PPA (plus unpaid accrued interest and the 5% premium) that has become due and will become fully due in September 2023, and/or obtain a waiver to defer the remaining repayment amount currently due to Yorkville, and/or regain compliance with the Nasdaq listing requirements, management will be required to seek other strategic alternatives, which may include, among others, a significant curtailment of our operations, a sale of certain of our assets, a sale of our entire company to strategic or financial investors, and/or allowing us to become insolvent by filing for bankruptcy protection under the provisions of the U.S. Bankruptcy Code.

These uncertainties raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on the basis that we will continue to operate as a going concern, which contemplates that we will be able to realize assets and settle liabilities and commitments in the normal course of business for the foreseeable future. Accordingly, the accompanying consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

### ***COVID-19 Pandemic***

The COVID-19 pandemic resulted in increased unemployment, commodity and stock market volatility during the acute phase of the epidemic. Increases in vaccination rates and lower levels of reported cases suggest that the worst part of the pandemic may have passed. Should a new or mutated variant arise that results in further measures to combat its spread, there could be an adverse material impact to our financial condition, operating results, and timing and amounts of cash flows.

Although we were able to operate continuously throughout 2021 and 2022, we implemented “work from home” policies as needed following local health recommendations for non-essential employees and employees whose roles are able to be performed remotely. Management of remote workers can present special challenges and productivity may not be as high for remote workers. Because certain elements of our operations (such as processing placental tissue, certain biological assays, translational research and storage of cord blood) cannot be performed remotely, we instituted controls and protocols including mandatory temperature checking, symptom assessment forms, incremental cleaning and sanitization of common surfaces to mitigate risks to employees. Although we have not experienced any material disruption to date, there can be no assurance that our mitigation measures will continue to be effective and that there will not be a disruption to an important element of our business in the future.

Due to a broad decline in economic activity and restrictions on physical access to certain medical facilities, we did experience a decrease in the net revenues of our degenerative disease business due to the pandemic. As for clinical trials, we did not cancel or postpone enrollment solely due to the risks of COVID-19. However, enrollment in the clinical trial evaluating CYNK-001 for AML experienced some delays in mid-2021 as sites assessed their safety protocols and experienced high volumes of COVID-19 patients. During 2022, we did not experience any significant impact to operations as a result of COVID-19.

The extent to which COVID-19 or any other health epidemic may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Accordingly, COVID-19 could have a material adverse effect on our business, results of operations, financial condition, and prospects.

## **Business Segments**

We manage our operations through an evaluation of three distinct business segments: Cell Therapy, Degenerative Disease, and BioBanking. The reportable segments were determined based on the distinct nature of the activities performed by each segment. Cell Therapy broadly refers to cellular therapies we are researching and developing, which are unproven and in various phases of development. All of the cell therapy programs fall into the Cell Therapy segment. We have no approved cell therapy product and have not generated revenue from the sale of cellular therapies to date. Degenerative Disease produces, sells and licenses products used in surgical and wound care markets, such as Biovance, Biovance 3L, Interfyl and Centaflex. We sell products in this segment both using our own sales force as well as independent distributors. We are developing additional tissue-based products for the Degenerative Disease segment. BioBanking collects stem cells from umbilical cords and placentas and provides storage of such cells on behalf of individuals for future use. We operate in the biobanking business primarily under the LifebankUSA brand. For more information about our reportable business segments refer to Note 19, “Segment Information” of our consolidated financial statements included elsewhere in this annual report.

## **Acquisitions and Divestitures**

Our current operations reflect strategic acquisitions and divestitures that we have made since formation. Additional details regarding the following acquisitions can be found in Note 1, “Nature of Business” to our consolidated financial statements for the year ended December 31, 2022 included elsewhere in this annual report.

In May 2017, we acquired HLI Cellular Therapeutics, LLC, or HLI CT, from HLI. HLI CT operated LifebankUSA, a private umbilical cord blood stem cell and cord tissue bank that offers parents the option to collect, process and cryogenically preserve newborn umbilical cord blood stem cells and cord tissue units. The HLI CT acquisition also provided us with rights to a portfolio of biomaterial assets, including Biovance and Interfyl. At the time of the HLI CT acquisition, Biovance and Interfyl were subject to an exclusive distribution arrangement with Alliqua Biomedical, Inc., or Alliqua. In May 2018, we acquired certain assets from Alliqua, including Alliqua’s biologic wound care business, which included the marketing and distribution rights to Biovance and Interfyl.

In August 2017, we acquired Anthrogenesis, a wholly-owned subsidiary of Celgene. The Anthrogenesis acquisition included a portfolio of pre-clinical and clinical stage assets, including key cellular therapeutic assets that we continue to develop. The Anthrogenesis acquisition gives us access to Anthrogenesis’ proprietary technologies and processes for the recovery of large quantities of high-potential stem cells and cellular therapeutic products derived from postpartum human placentas, each an Anthrogenesis Product. As part of the Anthrogenesis acquisition, some of the inventors of the Anthrogenesis Products and other key members of the Anthrogenesis Product development team joined us.

In October 2018, we acquired CariCord, a family cord blood bank established by ClinImmune Labs University of Colorado Cord Blood Bank and the Regents of the University of Colorado, a body corporate, for and on behalf of the University of Colorado School of Medicine.

## **Licensing Agreements**

In the ordinary course of business, we license in intellectual property and other rights from third parties and have also outlicensed our intellectual property and other rights, including in connection with our acquisitions and divestitures, described above. Additional details regarding our licensing agreements can be found in Note 16, “License and Distribution Agreements” to our audited consolidated financial statements for the year ended December 31, 2022 included elsewhere in this annual report on Form 10-K.

In September 2020, we entered into a license and transfer agreement with Sorrento. Henry Ji, Ph.D., a former member of Legacy Celularity’s board of directors, currently serves as President and Chief Executive Officer of Sorrento. Sorrento is also a significant stockholder of our company and invested, along with other significant stockholders, in a private placement of Class A common stock concurrently with the closing of the Business Combination, or the PIPE Financing. Pursuant to the Sorrento agreement, we obtained a worldwide license for the CD19 CAR construct that forms the basis of the genetic modification for CYCART-19. We are currently in the process of negotiating a supply agreement with Sorrento for the manufacturing and supply of the CD19 CAR construct licensed from Sorrento.

In August 2017, in connection with the Anthrogenesis acquisition, we entered into a license agreement, with Celgene, which has since been acquired by Bristol Meyers Squibb. Pursuant to the Celgene license, we granted Celgene a worldwide, royalty-free, fully-



paid up, non-exclusive license, without the right to grant sublicenses (other than to its affiliates), under Anthrogenesis' intellectual property in existence as of the date of the Celgene license or as developed by Celgene in connection with any transition services activities related to the merger for non-commercial pre-clinical research purposes, as well as to develop, manufacture, commercialize and fully exploit products and services that relate to the construction of any CAR, the modification of any T-cell or NK cell to express such a CAR, and/or the use of such CARs or T-cells or NK cells for any purpose, which commercial license is sublicensable. Either party may terminate the Celgene license upon an uncured material breach of the agreement by the other party or insolvency of the other party.

In August 2017, Legacy Celularity also issued shares of its Series X Preferred Stock to Celgene as merger consideration and entered into a CVR Agreement, with Celgene pursuant to which Legacy Celularity issued one contingent value right or CVR, in respect of each share of Legacy Celularity Series X Preferred Stock issued to Celgene in connection with the Anthrogenesis acquisition. The CVR Agreement entitles the holders of the CVRs to an aggregate amount, on a per program basis, of \$50 million in regulatory milestones and an aggregate \$125 million in commercial milestone payments with respect to certain of our investigational therapeutic programs. In addition, with respect to each such program and calendar year, the CVR holders will be entitled to receive a royalty equal to a mid-teen percentage of the annual net sales for such program's therapeutics from the date of the first commercial sale of such program's therapeutic in a particular country until the latest to occur of the expiration of the last to expire of any valid patent claim covering such program therapeutic in such country, the expiration of marketing exclusivity with respect to such therapeutic in such country, and August 2027 (i.e., the tenth anniversary of the closing of the acquisition of Anthrogenesis). No payments under the CVR Agreement have been made to date. We estimate the liability associated with the CVR quarterly. Changes to that liability include but are not limited to changes in our clinical programs, assumptions about the commercial value of those programs and the time value of money.

## **Components of Operating Results**

### ***Net revenues***

Net revenues include: (i) sales of biomaterial products, including Biovance, Biovance 3L, Interfyl, and Centaflex of which our direct sales are included in Product Sales and Rentals while sales through our network of distribution partners are included in License, royalty and other; (ii) the collection, processing and storage of umbilical cord and placental blood and tissue after full-term pregnancies, collectively, Services; and, (iii) license fees and royalties received under the license agreement with Sanuwave through the third quarter of 2021, collectively, License, royalty and other.

### ***Cost of revenues***

Cost of revenues consists of labor, material and overhead costs associated with our two existing commercial business segments, biobanking and degenerative disease. Biobanking costs include the cost of storage and transportation kits for newly banked materials as well as tank and facility overhead costs for cord blood and other units in storage. Degenerative disease costs include costs associated with procuring placentas, qualifying the placental material and processing the placental tissue into a marketable product. Costs in the degenerative disease segment include labor and overhead costs associated with the production of the Biovance, Biovance 3L, Interfyl and Centaflex product lines. Cost of revenues associated with direct sales are part of Product Sales and Rentals while cost of revenues associated with sales through our network of distribution partners are included in License, royalty and other.

### ***Research and development expense***

Our research and development expenses primarily relate to basic scientific research into placentally derived allogeneic cells, pre-clinical studies to support our current and future clinical programs in cellular medicine, clinical development of our NK cell programs and facilities, depreciation and other direct and allocated expenses incurred as a result of research and development activities. We incur expenses for third party CROs, that assist in running clinical trials, clinical trial supply costs, personnel expenses for research scientists, specialized chemicals and reagents used to conduct biologic research, expense for third party testing and validation and various overhead expenses including rent and facility maintenance expense. Basic research, research collaborations involving partners and research designed to enable successful regulatory submissions is critical to our current and future success in cell therapy. As a result of our reprioritization efforts, we anticipate that our research and development expenditures will decrease in the near term. The amount of our research and development expenditures will depend on numerous factors, including the timing of clinical trials, preliminary evidence of efficacy in clinical trials and the number of indications that we choose to pursue.

### ***Selling, general and administrative expense***

Selling, general and administrative expense consists primarily of personnel costs including salaries, bonuses, stock compensation and benefits for specialized staff that support our core business operations. Executive management, finance, legal, human resources and information technology are key components of selling, general and administrative expense and those expenses are recognized when incurred. We expect that as a result of our reprioritization efforts, we will see a decrease in our selling, general and administrative costs in the near term. The magnitude and timing of our selling, general and administrative costs will depend on the progress of clinical trials,



commercialization efforts for any approved therapies including the release of new products within the degenerative disease portfolio, changes in the regulatory environment or staffing needs to support our business strategy.

### ***Change in fair value of contingent consideration liability***

Because the acquisitions of Anthrogenesis from Celgene and HLI CT from HLI were accounted for as business combinations, we recognized acquisition-related contingent consideration on the balance sheet in accordance with the acquisition method of accounting. See “— Acquisitions and Divestitures” for more information. The fair value of contingent consideration liability is determined based on a probability-weighted income approach derived from revenue estimates and a probability assessment with respect to the likelihood of achieving regulatory and commercial milestone obligations and royalty obligations. The fair value of acquisition related contingent consideration is remeasured each reporting period with changes in fair value recorded in the consolidated statements of operations. Changes in contingent consideration fair value estimates result in an increase or decrease in our contingent consideration obligation and a corresponding charge or reduction to operating results. Key elements of the contingent consideration are regulatory milestone payments, sales milestone payments and royalty payments. Regulatory payments are due on regulatory approval of certain cell types in the United States and the European Union. Regulatory milestone payments are one time but are due prior to any potential commercial success of a cell type in a specific indication. Royalty payments are a percentage of net sales. Sales milestone payments are due when certain aggregate sales thresholds have been met. Management must use substantial judgment in evaluating the value of the contingent consideration. Estimates used by management include but are not limited to: (i) the number and type of clinical programs that we are likely to pursue based on the quality of our preclinical data, (ii) the time required to conduct clinical trials, (iii) the odds of regulatory success in those trials, (iv) the potential number of patients treatable for the indications in which we are successful and (v) the pricing of treatments that achieve commercial status. All of these areas involve substantial judgment on the part of management and are inherently uncertain.

## **Results of Operations**

### ***Comparison of Year Ended December 31, 2022 to December 31, 2021***

	<b>Year Ended December 31,</b>		<b>Percent</b>
	<b>2022</b>	<b>2021</b>	<b>Increase (Decrease)</b>
			<b>Increase (Decrease)</b>
<b>Net revenues:</b>			
Product sales and rentals	\$ 3,749	\$ 3,801	(52)
Services	5,512	5,522	(10)
License, royalty and other	8,714	12,012	(3,298)
Total revenues	17,975	21,335	(3,360)
<b>Operating expenses:</b>			
Cost of revenues (excluding amortization of acquired intangible assets)			
Product sales and rentals	2,353	3,528	(1,175)
Services	3,536	3,649	(113)
License, royalty and other	13,776	2,476	11,300
Research and development	78,363	88,353	(9,990)
Selling, general and administrative	66,021	71,341	(5,320)
Change in fair value of contingent consideration liability	(126,277)	(41,145)	(85,132)
Goodwill impairment	3,610	—	3,610
Amortization of acquired intangible assets	2,193	2,192	1
Total operating expense	43,575	130,394	(86,819)
Loss from operations	\$ (25,600)	\$ (109,059)	\$ 83,459

### ***Net Revenues and Cost of Revenues***

Net revenues for the year ended December 31, 2022 was \$18.0 million, a decrease of \$3.4 million, or 15.7%, compared to the prior year period. The decrease was primarily due to the prior year period including \$8.0 million of license revenue with Sanuwave. The decrease in license revenue was partially offset by a \$4.7 million increase in product sales to our distribution partners.

Cost of revenues for the year ended December 31, 2022 was \$19.7 million, an increase of \$10.0 million, or 103.7%, compared to the prior year period. The increase was primarily due to a \$4.6 million increase in production and material variances driven by increased spend in anticipation of degenerative disease sales that did not materialize in addition to an increase in cost of revenues driven by the increase in product sales to distribution partners.

### Research and Development Expenses

Research and development expenses for the year ended December 31, 2022 were \$78.4 million, a decrease of \$10.0 million, or 11.3%, compared to the prior year period. The decrease was primarily due to a \$19.4 million reduction in allocated costs as the prior year period included an allocated portion of stock-based compensation expense for awards granted to our board of directors and senior management partially offset by higher personnel costs of \$4.3 million and an increase in the Palantir platform fees of \$2.7 million.

### Selling, General and Administrative Expenses

Selling, general and administrative expenses for the year ended December 31, 2022 were \$66.0 million, a decrease of \$5.3 million, or 7.5%, compared to the prior year period. The decrease was primarily due to a \$25.9 million reduction in stock-based compensation expense related to awards granted to our board of directors and senior management in the prior year period, a portion of which was allocated to research and development expense, as well as a prior year charge related to a legal settlement with CTH, all of which were partially offset by higher personnel, professional services, and insurance costs to support operations of a public company.

### Goodwill Impairment

Goodwill impairment for the year ended December 31, 2022 was \$3.6 million compared to no impairment in the prior year period. The goodwill impairment was the result of lower forecasted sales and growth in the Degenerative Disease reporting unit.

### Change in Fair Value of Contingent Consideration Liability

The change in fair value of contingent consideration liability for the year ended December 31, 2022 was \$126.3 million, a decrease of \$85.1 million, or 206.9%. The decrease resulted from changes in market-based assumptions and underlying projections (for more information about changes in the fair value of contingent consideration liability refer to Note 4, “Fair Value of Financial Assets and Liabilities” of our consolidated financial statements included elsewhere in this annual report on Form 10-K).

### Other Income (Expense)

	Year Ended December 31,		Increase (Decrease)	Percent Increase (Decrease)
	2022	2021		
Interest income	\$ 365	\$ 332	\$ 33	9.9%
Interest expense	—	(3,171)	3,171	(100.0)%
Change in fair value of warrant liabilities	42,109	13,482	28,627	212.3%
Change in fair value of debt	(2,522)	—	(2,522)	100.0%
Other expense, net	(147)	(1,682)	1,535	(91.3)%
Total other income	<u>\$ 39,805</u>	<u>\$ 8,961</u>	<u>\$ 30,844</u>	344.2%

For the year ended December 31, 2022, other income (expense), increased by \$30.8 million compared to the prior year period. The increase was primarily due to a change in the fair value of the warrant liabilities due to the decrease in the price of our common stock (see Note 4, “Fair Value of Financial Assets and Liabilities” of our consolidated financial statements included elsewhere in this annual report on Form 10-K).

### Liquidity and Capital Resources

As of December 31, 2022, we had \$14.0 million of cash and cash equivalents and an accumulated deficit of \$645.5 million. Our primary use of our capital resources is funding our operating expenses, which consist primarily of funding the research and development of our cellular therapeutic candidates, and to a lesser extent, selling, general and administrative expenses.

As of the issuance date, we had approximately \$8.6 million of unrestricted cash and cash equivalents available to fund our operations and no available additional sources of outside capital to sustain our operations for a period of 12 months beyond the issuance date. These uncertainties raise substantial doubt about our ability to continue as a going concern. Refer to the *Going Concern* section above for further details.

To date, we have not had any cellular therapeutics approved for sale and have not generated any revenues from the sale of our cellular therapeutics. We generate limited revenues from our biobanking and degenerative disease businesses. We do not expect to generate any revenues from cellular therapeutic product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our therapeutic candidates, which we expect will take a number of years. If we obtain regulatory approval for any of our therapeutic candidates, we expect to incur significant commercialization expenses related to therapeutic sales,

marketing, manufacturing and distribution as our current commercialization efforts are limited to our biobanking and degenerative disease businesses. As a result, until such time, if ever, as we can generate substantial revenue from therapeutics and sales of our biomaterials products, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements, including drawdowns under the At-The-Market Sales Agreement, dated as of September 8, 2022, by and between us and BTIG, LLC, Oppenheimer & Co. Inc. and B. Riley Securities, Inc., or the ATM Program, and we continue to explore licensing and collaboration arrangements for our cellular therapeutics as well as distribution arrangements for our degenerative disease business including our distribution agreements with CH Trade Group, Tamer and AD Ports to support expansion abroad. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. Failure to obtain this necessary capital or address our liquidity needs may force us to delay, limit or terminate our operations, make further reductions in our workforce, discontinue our commercialization efforts for our biomaterials products as well as other clinical trial programs, liquidate all or a portion of our assets or pursue other strategic alternatives, and/or seek protection under the provisions of the U.S. Bankruptcy Code.

We expect to incur substantial expenses in the foreseeable future for the development and potential commercialization of our cellular therapeutic candidates, expansion of our degenerative disease business and ongoing internal research and development programs. At this time, we cannot reasonably estimate the nature, timing or aggregate amount of costs for our development, potential commercialization, and internal research and development programs. However, to complete our current and future preclinical studies and clinical trials, and to complete the process of obtaining regulatory approval for our therapeutic candidates, as well as to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our cellular therapeutic candidates, if approved, and biomaterials products we may require substantial additional funding in the future.

To date, inflation has not had a significant impact on our business. However, any significant increase in inflation and interest rates could have a significant effect on the economy in general and, thereby, could affect our future operating results.

### ***Cash Flows***

The following table summarizes our cash flows for the periods indicated:

	Year Ended December 31,		
	2022	2021	Change
Cash (used in)/provided by			
Operating activities	\$ (137,876)	\$ (110,096)	\$ (27,780)
Investing activities	(5,236)	(5,903)	667
Financing activities	119,838	98,562	21,276
Net change in cash, cash equivalents and restricted cash	\$ (23,274)	\$ (17,437)	\$ (5,837)

### ***Operating Activities***

Net cash used in operations for the year ended December 31, 2022 was \$27.8 million higher than the prior year period, primarily due to current year net income (loss) adjusted for non-cash items and build up of inventory partially offset by the prior year period including a reduction in deferred revenue related to the termination of the Sanuwave license agreement.

### ***Investing Activities***

We used \$5.2 million and \$5.9 million of net cash in investing activities during the years ended December 31, 2022 and 2021, respectively, which consisted of capital expenditures in each period offset by \$0.3 million in gross proceeds from promissory note in the prior year period.

### ***Financing Activities***

We generated \$119.8 million of net cash from financing activities for the year ended December 31, 2022, which consisted primarily of \$46.5 million in cash proceeds from the exercise of warrants to acquire 13,281,386 shares of common stock, \$27.4 million in cash proceeds from a May 2022 private placement, \$39.2 million in cash proceeds from the Yorkville pre-paid advance agreement, and \$6.0 million in cash proceeds from the sale of common stock in the ATM Program. For the year ended December 31, 2021, we generated \$98.6 million which consisted of \$108.8 million in cash proceeds from the merger with GX; the PIPE Financing; and Palantir Technologies, Inc., investment; partially offset by payments for professional services related to the aforementioned transactions of \$10.9 million. We also received and paid back \$5.0 million in short-term loans.

## **Critical Accounting Estimates**

Our significant accounting policies are summarized in Note 2, “Summary of Significant Accounting Policies,” included in our consolidated financial statements included elsewhere in this annual report on Form 10-K.

The preparation of our consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, assumptions related to the accounting for business combinations, goodwill and intangible impairment assessment, the valuation of inventory, contingent consideration, short-term debt, and contingent stock consideration, determination of incremental borrowing rates, accrual of research and development expenses, and the valuations of stock options and preferred stock warrants. We based our estimates on historical experience, known trends and other market-specific or other relevant factors that we believe to be reasonable under the circumstances. On an ongoing basis, management evaluates these estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

### ***Revenue Recognition***

We recognize revenue when control of the products and services is transferred to our customers in an amount that reflects the consideration we expect to receive from our customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied.

A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. We consider a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. Transaction prices of products or services are typically based on contracted rates with customers and to the extent that the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price utilizing the expected value method or the most likely amount, depending on the circumstances, to which we expect to be entitled.

Products within our Degenerative Disease segment generally do not contain multiple elements. We allow for a right of return for those products but to date returns have been minimal.

Under the license agreement with Sanuwave, we received a quarterly license fee and a defined royalty on each product sold. A credit was provided to Sanuwave for Biovance royalties up to the quarterly license fee. We recognized the quarterly license fee over each quarterly term based on the actual sales occurring over the period (until we terminated the license in the third quarter of 2021).

### ***Accounting for Business Combinations***

Accounting for business combinations requires us to make significant estimates and assumptions, especially at the acquisition date with respect to tangible and intangible assets acquired and liabilities assumed and pre-acquisition contingencies. We use our best estimates and assumptions to accurately assign fair value to the tangible and intangible assets acquired and liabilities assumed at the acquisition date as well as the useful lives of those acquired intangible assets. Examples of critical estimates in valuing certain of the intangible assets and goodwill we have acquired include but are not limited to developed technologies and in-process research and development. Our estimates may also impact our deferred income tax assets and liabilities. Unanticipated events and circumstances may occur that may affect the accuracy or validity of such assumptions, estimates or actual results.

### ***Valuation of Goodwill and Intangible Assets***

We have acquired and may continue to acquire significant intangible assets in connection with business combinations, which we record at fair value. The determination of fair value requires the use of forecasts, estimates and assumptions, which requires significant judgment by management. Each of these factors are subject to uncertainty and can significantly affect the value of the intangible asset.

Goodwill and indefinite-lived intangible assets are reviewed for impairment annually or when an event occurs that could result in an impairment. The impairment analysis requires the exercise of significant judgment by management and can involve both the assessment of qualitative factors (which are subject to uncertainty and can change significantly from period to period), as well as a quantitative. For our quantitative impairment tests, we use an estimated future cash flow approach that requires significant judgment with respect to future volume, revenue and expense growth rates, the selection of an appropriate discount rate, asset groupings and other assumptions and estimates. The estimates and assumptions used are subject to uncertainty. The use of alternative estimates and assumptions could increase or decrease the estimated fair value of the assets and could potentially impact our results of operations. Actual results may differ from our estimates.

### ***Contingent Consideration***

We have acquisition-related contingent consideration, which consists of potential milestone and royalty obligations, which was recorded in the consolidated balance sheets at our acquisition-date estimated fair value. We remeasure the fair value each reporting period, with changes recorded in the consolidated statements of operations. The determination of fair value requires the exercise of significant judgment and estimates by management. These include estimates and assumptions regarding the achievement and timing of milestones, forecasted revenues and assumptions utilized in calculating a discount rate. If management's assumptions prove to be inaccurate, it could result in changes to the contingent consideration liability and have a material effect on our results of operations.

### ***Warrant Liability***

Accounting for liability classified warrants requires management to exercise judgment and make estimates and assumptions regarding their fair value (for more information about the material inputs and assumptions used to value the liability classified warrants refer to Note 4, "Fair Value of Financial Assets and Liabilities" of our consolidated financial statements included elsewhere in this annual report on Form 10-K). The warrant liabilities are initially recorded at fair value upon the date of issuance and subsequently remeasured to fair value at each reporting date, with changes recognized in the consolidated statements of operations. Changes in the fair value of the liability classified warrants will continue to be recognized until the warrants are exercised, expire or qualify for equity classification.

### ***Convertible Note Receivable***

We have a convertible note receivable from the August 2020 disposition of the UltraMIST business. We use a bond valuation that employs a credit default model, which requires the use of estimates and judgment by management regarding: (i) the fair value and volatility of the issuer's common stock, (ii) probability and timing of converting the note, and (iii) risk-free interest rate. If our assumptions and estimates prove to be inaccurate, it could result in changes to the convertible note receivable and have a material effect on our results of operations.

### ***Stock-Based Compensation***

We recognize compensation expense related to stock options granted to employees and nonemployees based on the estimated grant date fair value and recognize forfeitures as they occur. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model for service-based and performance-based awards. For awards with market conditions, we utilize a Monte-Carlo model to estimate the fair value of those awards. The grant date fair value of the stock-based awards is recognized on a straight-line basis over the requisite service period, which is typically the vesting period of the respective awards. The Black-Scholes option-pricing model and Monte-Carlo model requires the use of highly subjective assumptions to determine the fair value of stock-based awards. See Note 14, "Stock-Based Compensation" to our audited consolidated financial statements included elsewhere in this annual report for information concerning certain of the specific assumptions used in applying the Black-Scholes option-pricing model to determine the estimated fair value of stock options granted during the years ended December 31, 2022 and 2021. Such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

### ***Leases***

We cannot readily determine the interest rate implicit in the lease, therefore, we use our incremental borrowing rate, or IBR, to measure lease liabilities. The IBR is the rate of interest that we would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use, or ROU, asset in a similar economic environment. The IBR therefore reflects what we 'would have to pay', which requires estimation when no observable rates are available or when they need to be adjusted to reflect the terms and conditions of the lease. We estimate the IBR using observable inputs (such as market interest rates) when available and are required to make certain entity and asset-specific estimates. The IBR used in the calculation of the present value of lease payments in calculating lease liabilities and the corresponding ROU requires the use of significant judgment by management.

### ***Short-Term Debt***

We elected the fair value option to account for the financial instrument as per the pre-paid advance agreement with Yorkville. The estimate of the fair value was determined using a binomial lattice model. The fair value measurement of the debt is determined using Level 3 inputs and assumptions unobservable in the market. Changes in the fair value of debt that is accounted for at fair value, inclusive of related accrued interest expense, are presented as gains or losses in the accompanying consolidated statements of operations and comprehensive income (loss) under change in fair value of debt. The portion of total changes in fair value of debt attributable to



changes in instrument-specific credit risk are determined through specific measurement of periodic changes in the discount rate assumption exclusive of base market changes and are presented as a component of comprehensive income (loss) in the accompanying consolidated statements of operations and comprehensive income (loss). The actual settlement of the short-term debt could differ from current estimates based on the timing of when and if Yorkville elects to convert amounts into common shares, potential cash repayment by us prior to maturity, and movements in our common share price.

### **Recent Accounting Pronouncements**

See Note 2, "Summary of Significant Accounting Policies" to our consolidated financial statements included elsewhere in this annual report on Form 10-K for information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent it has made one, of their potential impact on our financial condition of results of operations.

### **JOBS Act Accounting Election**

We are an "emerging growth company," as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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

We are exposed to market risks in the ordinary course of business. These risks primarily include interest rate sensitivities.

***Interest Rate Risk***

We had cash and cash equivalents of \$14.0 million as of December 31, 2022, which consists principally of cash held in commercial bank accounts and money market funds having an original maturity of less than three months. At December 31, 2022, substantially all cash and cash equivalents were held in either commercial bank accounts or money market funds. The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. Because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We have no variable interest debt outstanding as of December 31, 2022.

***Effects of Inflation***

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

**Item 8. Financial Statements and Supplementary Data.**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Celularity Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Celularity Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive income (loss), convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

### Going Concern

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

### Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Morristown, New Jersey

March 31, 2023

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

**CELULARITY INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share amounts)

	December 31,	
	2022	2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 13,966	\$ 37,240
Accounts receivable, net of allowance of \$1,789 and \$283 as of December 31, 2022 and December 31, 2021, respectively	4,452	2,745
Notes receivable	2,514	2,488
Inventory	5,308	9,549
Prepaid expenses and other current assets	7,262	7,078
Total current assets	33,502	59,100
Property and equipment, net	75,655	90,625
Goodwill	119,694	123,304
Intangible assets, net	120,994	123,187
Right-of-use assets - operating leases	13,060	—
Restricted cash	14,836	14,836
Inventory, net of current portion	22,949	2,721
Other long-term assets	376	355
Total assets	\$ 401,066	\$ 414,128
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,810	\$ 9,317
Accrued expenses and other current liabilities	16,402	11,661
Current portion of financing obligation	—	3,051
Short-term debt (\$37,603 at fair value and \$37,000 unpaid principal balance at December 31, 2022)	37,603	—
Deferred revenue	2,273	2,196
Total current liabilities	62,088	26,225
Deferred revenue, net of current portion	2,219	1,871
Acquisition-related contingent consideration	105,945	232,222
Noncurrent lease liabilities - operating	27,985	—
Financing obligations	—	28,085
Warrant liabilities	3,598	25,962
Deferred income tax liabilities	9	10
Other liabilities	321	335
Total liabilities	202,165	314,710
<b>Commitments and Contingencies (Note 12)</b>		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, none issued and outstanding at December 31, 2022; none authorized, issued and outstanding as of December 31, 2021	—	—
Common Stock, \$0.0001 par value, 730,000,000 shares authorized, 148,921,187 issued and outstanding as of December 31, 2022; 730,000,000 shares authorized, 124,307,884 issued and outstanding as of December 31, 2021	15	12
Additional paid-in capital	844,373	763,087
Accumulated other comprehensive income	9	—
Accumulated deficit	(645,496)	(663,681)
Total stockholders' equity	198,901	99,418
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 401,066	\$ 414,128

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

**CELULARITY INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**  
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	2021
Net revenues:		
Product sales and rentals	\$ 3,749	\$ 3,801
Services	5,512	5,522
License, royalty and other	8,714	12,012
Total revenues	17,975	21,335
Operating expenses:		
Cost of revenues (excluding amortization of acquired intangible assets)		
Product sales and rentals	2,353	3,528
Services	3,536	3,649
License, royalty and other	13,776	2,476
Research and development	78,363	88,353
Selling, general and administrative	66,021	71,341
Change in fair value of contingent consideration liability	(126,277)	(41,145)
Goodwill impairment	3,610	—
Amortization of acquired intangible assets	2,193	2,192
Total operating expenses	43,575	130,394
Loss from operations	(25,600)	(109,059)
Other income (expense):		
Interest income	365	332
Interest expense	—	(3,171)
Change in fair value of warrant liabilities	42,109	13,482
Change in fair value of debt	(2,522)	—
Other expense, net	(147)	(1,682)
Total other income	39,805	8,961
Net income (loss) before income taxes	14,205	(100,098)
Income tax expense	13	20
Net income (loss)	\$ 14,192	\$ (100,118)
Change in fair value of debt due to change in credit risk, net of tax	9	—
Other comprehensive income	9	—
Comprehensive income (loss)	\$ 14,201	\$ (100,118)
Share information:		
Net income (loss) per share – basic	\$ 0.10	\$ (1.49)
Weighted average shares outstanding – basic	139,907,029	67,057,278
Net income (loss) per share – diluted	\$ 0.09	\$ (1.49)
Weighted average shares outstanding – diluted	149,830,016	67,057,278

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



**CELULARITY INC.**

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

**CELULARITY INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash flow from operating activities:</b>		
Net income (loss)	\$ 14,192	\$ (100,118)
Adjustments to reconcile net income (loss) to net cash used in operations:		
Depreciation and amortization	9,436	8,817
Non cash lease expense	(59)	—
Deferred income taxes	(1)	(1,353)
Provision for doubtful accounts	1,877	298
Change in fair value of warrant liabilities	(42,109)	(13,482)
Inventory reserve for obsolescence	904	—
Goodwill impairment	3,610	—
Stock-based compensation expense	15,856	40,010
Change in fair value of contingent consideration	(126,277)	(41,145)
Change in fair value of debt	2,522	—
Issuance of common stock to settle liability with CTH	—	5,333
Change in fair value of contingent stock consideration	186	—
Other, net	(37)	2,627
Changes in assets and liabilities:		
Accounts receivable	(3,584)	(1,909)
Inventory	(16,891)	(6,422)
Prepaid expenses and other assets	49	3,068
Sale of net operating loss and R&D tax credits	—	1,356
Accounts payable	(2,948)	3,007
Accrued expenses and other liabilities	4,710	(1,801)
Right-of-use assets and lease liabilities	263	—
Deferred revenue	425	(8,382)
Net cash used in operating activities	(137,876)	(110,096)
<b>Cash flow from investing activities:</b>		
Capital expenditures	(5,236)	(6,203)
Proceeds from promissory note	—	300
Net cash used in investing activities	(5,236)	(5,903)
<b>Cash flow from financing activities:</b>		
Proceeds from the exercise of warrants	46,491	—
Proceeds from short-term debt	39,200	—
Proceeds from the sale of common stock in ATM offering	6,519	—
Payments of ATM offering costs and commissions	(498)	—
Proceeds from short term borrowings - related party	—	5,000
Payment of short term borrowings - related party	—	(5,000)
Cash received from GX Acquisition Corp. on recapitalization	—	5,386
Proceeds from Palantir investment	—	20,000
Proceeds from PIPE financing	30,000	83,400
Proceeds from the exercise of stock options	862	638
Tax withholding on vesting of restricted stock units	(132)	—
Payments of PIPE/SPAC related costs	(2,604)	(10,862)
Net cash provided by financing activities	119,838	98,562
Net decrease in cash, cash equivalents and restricted cash	(23,274)	(17,437)
Cash, cash equivalents and restricted cash at beginning of year	52,076	69,513
Cash, cash equivalents and restricted cash at end of year	<u>\$ 28,802</u>	<u>\$ 52,076</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ —	\$ 146
Cash paid for income taxes	\$ —	\$ —
<b>Supplemental non-cash investing and financing activities:</b>		
Property and equipment included in accounts payable and accrued expenses	\$ (683)	\$ (970)
Common stock issued for short-term debt conversion	\$ 4,099	\$ —
Recapitalization from GX Acquisition Corp. merger	\$ —	\$ 550,113
Cancellation of treasury stock	\$ —	\$ 256
Non-cash assets acquired from merger with GX Acquisition Corp.	\$ —	\$ 163
Warrant liability assumed from the merger with GX Acquisition Corp.	\$ —	\$ 59,202
Issuance of common stock as payment for PIPE/merger related costs	\$ —	\$ 10,795
Reclassification of warrant liabilities to equity	\$ —	\$ 96,398
Reclass of offering costs paid in prior year	\$ —	\$ 153
Reclassification of option liabilities to equity	\$ 441	\$ —

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

**CELULARITY INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(In thousands, except share and per share amounts)**

**1. Nature of Business**

Celularity Inc., (“Celularity” or the “Company”), formerly known as GX Acquisition Corp. (“GX”), was a blank check company incorporated in Delaware on August 24, 2018. The Company was formed for the purpose of effectuating a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or other similar business combination with one or more businesses.

On July 16, 2021 (the “Closing Date”), the Company consummated the previously announced merger pursuant to the Merger Agreement and Plan of Reorganization, dated January 8, 2021 (the “Merger Agreement”), by and among GX, Alpha First Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of GX (“First Merger Sub”), Celularity LLC (f/k/a Alpha Second Merger Sub LLC), a Delaware limited liability company and a direct, wholly owned subsidiary of GX (“Second Merger Sub”), and the entity formerly known as Celularity Inc., incorporated under the laws of the state of Delaware on August 29, 2016 (“Legacy Celularity”). Upon completion of the merger transaction, GX changed its name to Celularity Inc. The business combination was accounted for as a reverse recapitalization in conformity with accounting principles generally accepted in the United States (see Note 3).

***Description of Business***

Celularity is a biotechnology company leading the next evolution in cellular medicine by developing off-the-shelf placental-derived allogeneic cell therapies for the treatment of cancer and immune and infectious diseases. Celularity is developing a pipeline of off-the-shelf placental-derived allogeneic cell therapy product candidates including T cells engineered with a chimeric antigen receptor (“CAR”), natural killer (“NK”), cells, and mesenchymal-like adherent stromal cells (“MLASCs”) and exosomes. These therapeutic candidates target indications across cancer, infectious and degenerative diseases. Celularity believes that by harnessing the placenta’s unique biology and ready availability, it will be able to develop therapeutic solutions that address a significant unmet global need for effective, accessible and affordable therapeutics. Celularity also actively develops and markets biomaterial products derived from the placenta. Prior to 2023, Celularity marketed those products domestically primarily serving the orthopedic and wound care markets. Celularity now intends to market placental biomaterials outside of the U.S. with an initial focus on markets in the Middle East and North Africa. Celularity’s biomaterials business today is comprised primarily of the sale of its Biovance and Interfyl products, directly or through its distribution network. Biovance is decellularized, dehydrated human amniotic membrane derived from the placenta of a healthy, full-term pregnancy. It is an intact, natural extracellular matrix that provides a foundation for the wound regeneration process and acts as a scaffold for restoration of functional tissue. Interfyl is human connective tissue matrix derived from the placenta of a healthy, full-term pregnancy. It is used by a variety of medical specialists to fill soft tissue deficits resulting from wounds, trauma, or surgery. Celularity is developing new placental biomaterial products to deepen the commercial pipeline beyond Biovance and Interfyl. The Company also plans to leverage its core expertise in cellular therapeutic development and manufacturing to generate revenues by providing contract manufacturing and development services to third parties. The initial focus of this new service offering will be to assist development stage cell therapy companies with the development and manufacturing of their therapeutic candidates for clinical trials. In January 2023, the Company announced reprioritization of efforts which resulted in a reduction of approximately one-third of its workforce as of March 2023.

Celularity is headquartered in Florham Park, NJ. Legacy Celularity acquired Anthrogenesis Corporation (“Anthrogenesis”) in August 2017 from Celgene Corporation (“Celgene”), a global biotechnology company that merged with Bristol Myers Squibb Company. Previously, Anthrogenesis operated as Celgene Cellular Therapeutics, Celgene’s cell therapy division. Celularity currently has three active clinical trials and is in the process of working with the U.S. Food and Drug Administration (“FDA”) to resolve its questions on an investigational new drug application (“IND”) it submitted in the first quarter of 2022 before commencing an additional clinical trial.

The Celularity IMPACT platform capitalizes on the benefits of placenta-derived cells to target multiple diseases, and provides seamless integration, from bio sourcing through manufacturing cryopreserved and packaged allogeneic cells at its purpose-built U.S.-based 147,215 square foot facility. Celularity’s placental-derived cells are allogeneic, meaning they are intended for use in any patient, as compared to autologous cells, which are derived from an individual patient for that patient’s use. From a single source material, the postpartum human placenta, the Company derives five allogeneic cell or extracellular vesicle types: T cells, unmodified NK cells, genetically modified NK cells, MLASCs and exosomes, which are used in seven key cell therapeutic programs—CYCART-19, CYCART-201, CYNK-001, CYNK-301, CYNK-302, APPL-001, and pEXO-001. CYCART-19 is a placental-derived CAR-T cell therapy, in development for the treatment of B-cell malignancies, initially targeting the cluster of differentiation 19, or CD19, receptor, the construct and related CARs for which are in-licensed from Sorrento. In the first quarter of 2022, the Company submitted an IND to investigate CYCART-19 for treatment of B-cell malignancies and in late May 2022, received formal written communication from FDA requesting additional information before it can proceed with the planned Phase 1/2 clinical trial. The Company is in the process of working with the FDA in an effort to resolve its questions as promptly as possible. The Company expects to commence the trial, if the IND is cleared by FDA, and sufficient funding is available, in second half of 2023. The Company will also progress CYCART-201, its

genetically modified T-cell expressing CD16 with a T-cell receptor, or TCR, knockout in combination with monoclonal antibodies, or mAbs, in non-Hodkin's lymphoma, or NHL, and in solid tumors. CYNK-001 is a placental-derived unmodified NK cell. In 2022, the Company had active and approved clinical trials under development for the treatment of acute myeloid leukemia, or AML, a blood cancer, and for glioblastoma multiforme, or GBM, a solid tumor cancer. CYNK-001 is currently in an active Phase 1 trial for AML. The Company will also advance CYNK-301 as its next generation CAR-NK that has the potential to overcome some of the challenges faced by NK therapies in treating relapse refractory AML, or rAML. Due to a need to prioritize corporate resources, in January 2023 the Company announced its intention to cease recruitment in the GBM trial. The Company will however, continue to advance its solid tumor research programs. CYNK-302 is a next generation CAR-NK being developed in solid tumors with an initial focus on non-small cell lung cancer, or NSCLC, an area of continued high unmet need. APPL-001 is a placenta-derived MLASC being developed for the treatment of Crohn's disease, and other degenerative diseases. pExo-001 is placenta-derived exosome being developed for the treatment of osteoarthritis.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with governmental regulations and the ability to secure additional capital to fund operations. Drug candidates currently under development will require significant additional approval prior to commercialization, including extensive preclinical and clinical testing and regulatory approval. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

### *Acquisitions*

Shortly after Legacy Celularity's incorporation in 2016, it completed four business combinations. Legacy Celularity did not have any significant activities prior to its acquisitions.

On May 31, 2017, Legacy Celularity acquired HLI Cellular Therapeutics, LLC ("HLI CT") from Human Longevity Inc. ("HLI"). HLI CT operated LifebankUSA, a private umbilical cord blood stem cell and cord tissue bank that offers parents the option to collect, process and cryogenically preserve newborn umbilical cord blood stem cells and cord tissue units. The HLI CT acquisition also provided Legacy Celularity with rights to a portfolio of biomaterial assets, including Biovance® and Interfyl® as well as PSC-100, a development-stage placental stem cell program. Prior to the acquisition, HLI entered into a Supply Agreement and a License, Marketing and Development Agreement (collectively, "the HLI Agreements") with Alliqua Biomedical Inc. ("Alliqua"). The HLI Agreements gave Alliqua exclusive rights to market and distribute Biovance® and Interfyl®. Rights, title and interest into the HLI Agreements transferred to the Company as a result of the HLI CT acquisition. In aggregate, the fair value of the consideration to acquire HLI CT was \$28,876. The acquisition led to goodwill and intangible assets including in-process research and development ("IPR&D") and a licensing agreement.

On August 15, 2017, Legacy Celularity executed a Merger Agreement with Celgene whereupon it acquired Anthrogenesis, a wholly-owned subsidiary of Celgene (the "Anthrogenesis Merger Agreement"). The Anthrogenesis acquisition included a portfolio of pre-clinical and clinical stage assets, including key cellular therapeutic assets in immuno-oncology, inflammatory and age-related diseases, that Legacy Celularity continues to develop. The Anthrogenesis acquisition gives Legacy Celularity access to Anthrogenesis' proprietary technologies and processes for the recovery of large quantities of high-potential stem cells and cellular therapeutic products derived from postpartum human placentas (each an "Anthrogenesis Product"). As part of the Anthrogenesis acquisition, some of the inventors of the Anthrogenesis Products and other key members of the Anthrogenesis Product development team joined Legacy Celularity. In aggregate, the fair value of the consideration to acquire Anthrogenesis was \$346,430. The acquisition led to goodwill and intangible assets including IPR&D and a licensing agreement and contingent value rights ("CVR") agreement.

In August 2017, Legacy Celularity issued shares of its Series X Preferred Stock to Celgene as merger consideration and entered into a contingent value rights agreement (the "CVR Agreement") with Celgene pursuant to which it issued one CVR in respect of each share of Series X Preferred Stock issued to Celgene in connection with the Anthrogenesis acquisition. The CVR Agreement entitles the holders of the CVRs to an aggregate amount, on a per program basis, of \$50,000 in regulatory milestones and an aggregate \$125,000 in commercial milestone payments with respect to certain programs. In addition, with respect to each such program and calendar year, the CVR holders will be entitled, with respect to a given calendar year and program, to receive a royalty equal to a mid-teen percentage of the annual net sales for such program, from the date of the first commercial sale of such program's product in a particular country until the latest to occur of the expiration of the last to expire of any valid patent claim covering such program product in such country, the expiration of marketing exclusivity with respect to such product in such country, and August 2027 (i.e., the tenth anniversary of the closing of the acquisition of Anthrogenesis). Celularity estimates the liability associated with the CVR quarterly. Changes to that liability include but are not limited to changes in Celularity clinical programs, assumptions about the commercial value of those programs and the time value of money.

On May 7, 2018, the Company completed an Asset Purchase Agreement with Alliqua, a regenerative technologies company that commercializes regenerative medical products (the "Alliqua APA"). The Alliqua APA included the acquisition of Alliqua's biologic

wound care business, including the marketing and distribution rights to Biovance® and Interfyl® as well as a Class II medical device, the MIST® and UltraMIST® Therapy Systems. In connection with the Alliqua APA, the Company paid cash consideration of \$29,000. The Alliqua acquisition led to goodwill and intangible assets. No debt or significant liabilities were assumed by the Company.

On October 5, 2018, the Company acquired CariCord Inc. (“CariCord”), a family cord blood bank established by ClinImmune Labs University of Colorado Cord Blood Bank (“ClinImmune Labs”) and the Regents of the University of Colorado, a body corporate, for and on behalf of the University of Colorado School of Medicine (the “University of Colorado”). In the aggregate, the fair value of the consideration to acquire CariCord was \$9,326. The acquisition led to goodwill and intangible assets.

## **COVID-19**

On March 10, 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The virus and actions taken to mitigate its spread have had, and are expected to continue to have, a broad adverse impact on the economies and financial markets of many countries, including the geographical areas in which the Company operates and conducts its business, and those in which the Company’s partners operate and conduct their business. The Company is currently following the recommendations of local health authorities to minimize exposure risk for its team members and visitors. However, the scale and scope of this pandemic is unknown and the duration of the business disruption and related financial impact cannot be reasonably estimated at this time. While management has implemented specific business continuity plans to reduce the potential impact of COVID-19, there is no guarantee that the Company’s continuity plans will be successful.

Although the Company was able to operate continuously since the pandemic began, the Company implemented work-from-home policies as needed following local health recommendations for non-essential employees and employees whose roles are able to be performed remotely. Because certain elements of the Company’s operations (such as processing placental tissue, certain biological assays, translational research and storage of cord blood) cannot be performed remotely, the Company instituted controls and protocols including mandatory temperature checking, symptom assessment forms, incremental cleaning and sanitization of common surfaces to mitigate risks to employees.

Due to a broad decline in economic activity and restrictions on physical access to certain medical facilities, the Company did experience a decrease in the net revenues of its degenerative disease business due to the pandemic in 2021. As for clinical trials, the Company did not cancel or postpone enrollment solely due to the risks of COVID-19. However, enrollment in the clinical trial evaluating CYNK-001 for AML experienced some delays in the first half of 2020 as sites assessed their safety protocols and experienced high volumes of COVID-19 patients. Enrollment has continued in the AML trial and remains ongoing. As a result, during 2020 the Company had a year-over-year increase in research and development expenses notwithstanding the enrollment delays. The Company also initiated a clinical trial evaluating CYNK-001 in patients with COVID-19, which necessitated additional research and development and project management resources. The Company believes that it would have deployed its human and capital resources to other efforts, such as its CYCART-19 clinical development program, had the COVID-19 pandemic not struck.

COVID-19 did not have a material negative impact on oncology clinical trial patient accrual rates during 2021 and 2022. During 2021, Celularity continued to utilize mandatory temperature checking and symptom assessment forms and, commencing with the third quarter of 2021, instituted additional safety protocols for unvaccinated employees. Celularity also utilized a liaison to help schedule vaccination appointments for employees.

The extent to which COVID-19 or any other health epidemic may impact the Company’s results will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Accordingly, COVID-19 could have a material adverse effect on the Company’s business, results of operations, financial condition, and prospects.

## **Going Concern**

In accordance with Accounting Standards Update (“ASU”) No. 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40) (“ASU 205-40”), the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

As an emerging clinical-stage biotechnology company, Celularity is subject to certain inherent risks and uncertainties associated with the development of an enterprise. In this regard, since the Company’s inception, substantially all of management’s efforts have been devoted to making investments in research and development including basic scientific research into placentally-derived allogeneic cells, pre-clinical studies to support its current and future clinical programs in cellular therapeutics, and clinical development of its cell programs as well as facilities and selling, general and administrative expenses that support its core business operations (collectively the “investments”), all at the expense of the Company’s short-term profitability. The Company has historically funded these investments



through limited revenues generated from its biobanking and degenerative disease businesses and issuances of equity and debt securities to public and private investors (these issuances are collectively referred to as “outside capital”). Notwithstanding these efforts, management can provide no assurance that the Company’s research and development and commercialization efforts will be successfully completed, or that adequate protection of the Company’s intellectual property will be adequately maintained. Even if these efforts are successful, it is uncertain when, if ever, the Company will generate significant sales or operate in a profitable manner to sustain the Company’s operations without needing to continue to rely on outside capital. Continued decline in the Company’s share price could result in impairment of goodwill or long-lived assets in a future period.

As of the date the accompanying consolidated financial statements were issued (the “issuance date”), management evaluated the significance of the following adverse conditions and events in accordance with ASU 205-40:

- Since its inception, the Company has incurred significant operating losses and used net cash outflows from operations. For the year ended December 31, 2022, the Company incurred a net operating loss of \$25,600 and used net cash out in operations of \$137,876. As of December 31, 2022, the Company had an accumulated deficit of \$645,496. The Company expects to continue to incur significant operating losses and use net cash in operations for the foreseeable future.
- As of the issuance date, the Company had approximately \$8,600 of unrestricted cash and cash equivalents available to fund the Company’s operations and no available additional sources of outside capital to sustain the Company’s operations for a period of 12 months beyond the issuance date.
- The Company expects to incur substantial expenditures to fund its investments for the foreseeable future. In order to fund these investments, the Company will need to secure additional sources of outside capital. While the Company is actively seeking to secure additional outside capital (and has historically been able to successfully secure such capital), as of the issuance date, no additional outside capital has been secured or was deemed probable of being secured. In addition, management can provide no assurance that the Company will be able to secure additional outside capital in the future or on terms that are acceptable to the Company. Absent an ability to secure additional outside capital in the very near term, the Company will be unable to meet its obligations as they become due over the next 12 months beyond the issuance date.
- As disclosed in Note 10, the Company had approximately \$37,000 of borrowings outstanding under a financing arrangement referred to as the PPA with a private investor, Yorkville, as of December 31, 2022. These borrowings are scheduled to mature in September 2023 absent Yorkville’s election to convert some or all of the borrowings into shares of the Company’s common stock. On February 22 2023, Yorkville provided notice to the Company that a “triggering event” had occurred, as provided for under the terms of the PPA. As a result of this triggering event, the Company is now required to make repayments of \$6,000 per month plus a payment premium of 5% of the principal amount being paid and all outstanding accrued and unpaid interest (collectively the “repayment amount”). On March 24, 2023, the Company paid \$1,950 of the repayment amount owed to Yorkville and is currently seeking to secure a waiver from Yorkville to, among other things, defer the remaining repayment amount owed of approximately \$11,000. However, a waiver has not been secured as of the issuance date. If the Company fails to secure a waiver from Yorkville and fails to pay the remaining repayment amount currently due, Yorkville could deem such non-payment an event of default under the PPA. If Yorkville deems such non-payment an event of default, Yorkville may, at its discretion, exercise its rights and remedies as provided in the PPA which may include, among others, accelerating the repayment of the total principal due under the PPA (\$37,000 as of December 31, 2022 or approximately \$32,600 as of issuance date), plus accrued and unpaid interest and the 5% premium, and/or force the Company to seek protection under the provisions of the U.S. Bankruptcy Code.
- On March 14, 2023, the Company received a notice from the Nasdaq notifying the Company that they no longer comply with the minimum bid price requirement for continued listing on the Nasdaq Capital Market because the closing bid price for the Company’s Class A common stock has fallen below \$1.00 per share for the last 30 consecutive business days. The Company has a period of 180 calendar days, or until September 11, 2023, to regain compliance with the minimum bid price requirement. The Company intends to actively monitor the closing bid price of its Class A common stock and will evaluate available options to regain compliance with the minimum bid requirement. However, management can provide no assurance that the Company will be able to regain compliance with the minimum bid requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance, or maintain compliance with the other Nasdaq listing requirements. In the event the Company is unable to regain or maintain compliance with the Nasdaq listing requirements, the liquidity of the Company’s publicly traded securities will be adversely affected and the Company’s ability to secure additional outside capital through public markets will be adversely affected.

- In the event the Company is unable to secure additional outside capital to fund the Company's obligations when they become due over the next 12 months beyond the issuance date, which includes the funds needed to repay the outstanding principal on the PPA (plus unpaid accrued interest and the 5% premium) that has become due and will become fully due in September 2023, and/or obtain a waiver to defer the remaining repayment amount currently due to Yorkville, and/or regain compliance with the Nasdaq listing requirements, management will be required to seek other strategic alternatives, which may include, among others, a significant curtailment of the Company's operations, a sale of certain of the Company's assets, a sale of the entire Company to strategic or financial investors, and/or allowing the Company to become insolvent by filing for bankruptcy protection under the provisions of the U.S. Bankruptcy Code.

These uncertainties raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements have been prepared on the basis that the Company will continue to operate as a going concern, which contemplates that the Company will be able to realize assets and settle liabilities and commitments in the normal course of business for the foreseeable future. Accordingly, the accompanying consolidated financial statements do not include any adjustments that may result from the outcome of these uncertainties.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The consolidated financial statements include the accounts of wholly owned subsidiaries, after elimination of intercompany accounts and transactions. The consolidated financial information presented herein reflects all financial information that, in the opinion of management, is necessary for a fair statement of financial position, results of operations and cash flows for the periods presented.

### ***Use of Estimates***

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, assumptions related to the Company's goodwill and intangible impairment assessment, the valuation of inventory, contingent consideration, short-term debt, determination of incremental borrowing rates, accrual of research and development expenses, and the valuations of stock options and stock warrants. The Company based its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

### ***Fair Value Measurements***

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

### ***Cash and Cash Equivalents***

Cash and cash equivalents consist principally of cash held in commercial bank accounts, money market funds and U.S. Treasury securities having an original maturity of less than three months. The Company considers all highly liquid investments with maturities

of three months or less at the date of acquisition to be cash equivalents. At December 31, 2022 and 2021, substantially all cash and cash equivalents were held in either commercial bank accounts or money market funds.

### ***Restricted Cash***

As of December 31, 2022 and 2021, the Company maintained a letter of credit of \$14,836 for the benefit of the landlord of a leased property, which the Company classified as restricted cash (non-current) on its consolidated balance sheets.

### ***Inventory***

Inventory is stated at the lower of cost or market (net realizable value), with cost being determined on a first-in, first-out basis. Prior to initial approval from the FDA or other regulatory agencies, the Company expenses costs relating to the production of inventory in the period incurred. After such time as the product receives initial regulatory approval, the Company capitalizes the inventory costs related to the product. The Company continues to expense costs associated with clinical trial supply costs as research and development expense.

The Company periodically analyzes the inventory levels to determine whether there is any obsolete, expired, or excess inventory. If any inventory is (i) expected to expire prior to being sold, (ii) has a cost basis in excess of its net realizable value, (iii) is in excess of expected sales requirements as determined by internal sales forecasts, or (iv) fails to meet commercial sale specifications, the inventory is written-down through a charge to cost of revenues. The determination of whether inventory costs will be realizable requires estimates by management of future expected inventory requirements, based on sales forecasts. If actual market conditions are less favorable than those projected by management, inventory write-downs may be required. Inventory, net of current portion on the Company's consolidated balance sheets includes inventory expected to remain on hand beyond one year.

### ***Property and Equipment***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset, as follows:

	Estimated Useful Life
Building	26 years
Furniture and fixtures	5 - 7 years
Lab equipment	5 years
Computer equipment	3 years
Software	3 years
Leasehold improvements	shorter of the estimated useful life or the lease term

Estimated useful lives are periodically assessed to determine if changes are appropriate. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost of these assets and related accumulated depreciation or amortization are eliminated from the consolidated balance sheets and any resulting gains or losses are included in the consolidated statements of operations in the period of disposal. Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service.

### ***Impairment of Long-Lived Assets***

Long-lived assets consist of property, plant and equipment, operating right-of-use assets, and definite-lived intangible assets. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. Due to the goodwill impairment recognized during the fourth quarter of 2022 relating to the Degenerative Disease reporting unit discussed below and in Note 8, we performed a recoverability test on long-lived assets and concluded no additional impairment to be recognized as result of this test. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2022 and 2021.

## ***Business Combinations***

The purchase price allocation for business combinations requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired and liabilities assumed based on their respective fair values. Under Accounting Standards Codification ("ASC") 805, *Business Combinations*, the Company first determines whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this threshold is met, the single asset or group of assets, as applicable, is not a business. If the single asset or group of similar assets does not meet the threshold, an entity must next evaluate whether both an input and substantive process are present.

The Company accounts for business combinations using the acquisition method of accounting. Application of this method of accounting requires that (i) identifiable assets acquired (including identifiable intangible assets) and liabilities assumed generally be measured and recognized at fair value as of the acquisition date and (ii) the excess of the purchase price over the net fair value of identifiable assets acquired and liabilities assumed be recognized as goodwill, which is not amortized for accounting purposes but is tested for impairment at least annually. Acquired IPR&D is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. Transaction costs related to business combinations are expensed as incurred.

Determining the fair value of assets acquired and liabilities assumed in a business combination requires management to use significant judgment and estimates, especially with respect to intangible assets. Critical estimates in valuing certain identifiable assets include, but are not limited to, the selection of valuation methodologies, estimates of future revenue and cash flows, expected long-term market growth, future expected operating expenses, costs of capital and appropriate discount rates. Management's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and, as a result, actual results may differ materially from estimates.

During the measurement period, which extends no later than one year from the acquisition date, the Company may record certain adjustments to the carrying value of the assets acquired and liabilities assumed with the corresponding offset to goodwill. After the measurement period, all adjustments are recorded in the consolidated statements of operations as operating expenses or income.

Acquisition-related contingent consideration, which consists of potential milestone and royalty obligations (see Note 12), was recorded in the consolidated balance sheets at its acquisition-date estimated fair value, in accordance with the acquisition method of accounting. The fair value of the acquisition-related contingent consideration is remeasured each reporting period, with changes in fair value recorded in the consolidated statements of operations. The fair value measurement is based on significant inputs not observable by market participants and thus represents a Level 3 input in the fair value hierarchy (see Note 4).

## ***Asset Acquisitions***

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. In an asset acquisition, the cost allocated to acquire IPR&D with no alternative future use is charged to research and development expense at the acquisition date.

## ***In-Process Research and Development***

The fair value of IPR&D acquired through a business combination is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset is reclassified to a definite-lived asset and amortized over its estimated useful life.

The fair value of an IPR&D intangible asset is typically determined using an income approach whereby management forecasts the net cash flows expected to be generated by the asset over its estimated useful life. The net cash flows reflect the asset's stage of completion, the probability of technical success, the projected costs to complete, expected market competition, and an assessment of the asset's life-cycle. The net cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk factors associated with the cash flow streams.

Indefinite-lived IPR&D is not subject to amortization but is tested annually for impairment or more frequently if there are indicators of impairment. The Company tests its indefinite-lived IPR&D annually for impairment during the fourth quarter. In testing indefinite-lived IPR&D for impairment, the Company has the option to first assess qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that its fair value is less than its carrying amount, or the Company can perform a quantitative impairment analysis to determine the fair value of the indefinite-lived IPR&D without performing a qualitative assessment. Qualitative factors that the Company considers include significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If the Company chooses to first assess qualitative factors and the Company determines that it is more likely than not that the fair value of the indefinite-lived IPR&D is less than its carrying amount, the Company would then determine the fair value of the indefinite-lived IPR&D. Under either approach, if the fair value of the indefinite-lived IPR&D is less than its carrying amount, an impairment charge is recognized in the consolidated statements of operations. During



the years ended December 31, 2022 and 2021, the Company did not recognize an impairment charge related to its indefinite-lived IPR&D.

### ***Goodwill***

Goodwill represents the excess of the fair value of the consideration transferred over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. Goodwill is not subject to amortization but is tested annually for impairment or more frequently if there are indicators of impairment. The Company typically tests its goodwill annually for impairment in the fourth quarter of each year.

The Company manages its operations through an evaluation of three different operating segments: Cell Therapy, Degenerative Disease and BioBanking (see Note 19). The Company determined that the operating segments represented the reporting units.

In testing goodwill for impairment, the Company has the option to first assess qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that the fair value of the reporting unit was less than its carrying amount, or the Company can perform a quantitative impairment analysis without performing the qualitative assessment. Examples of such events or circumstances considered in the Company's qualitative assessment include, but are not limited to, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition. If the Company chooses to first assess qualitative factors and the Company determines that it is more likely than not that the fair value of its reporting unit is less than its carrying amount, the Company would then perform the quantitative impairment test. The quantitative test starts with comparing the fair value of the reporting unit to the carrying amount of a reporting unit, including goodwill. If the fair value of the reporting unit exceeds the carrying amount, no impairment loss is recognized. However, if the fair value of the reporting unit is less than its carrying value, the Company would recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, not to exceed the total amount of goodwill allocated to the reporting unit. During the year ended December 31, 2022, the Company recognized goodwill impairment of \$3,610 relating to the Degenerative Disease reporting unit (See Note 8) in our consolidated statements of operations. During the year ended December 31, 2021, no goodwill impairment was recognized.

### ***Warrants Liabilities***

We account for the public warrants and private placement warrants in accordance with the guidance contained in ASC 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity," under which the public warrants and private placement warrants do not meet the criteria for equity treatment and must be recorded as liabilities. Accordingly, we classify the public warrants and private placement warrants as liabilities at their fair value and adjust the public warrants and private placement warrants to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other (expense) income in the consolidated statements of operations. The private warrants were initially and subsequently valued using a Black-Scholes option pricing model, which is considered to be a Level 3 fair value measurement. The public warrants are valued based on the quoted market price as of each relevant reporting date.

Prior to the business combination with GX (see Notes 1 and 3), the Company classified warrants for the purchase of shares of its convertible preferred stock (see Note 13) as liabilities on its consolidated balance sheets as these warrants were freestanding financial instruments that may have required the Company to transfer assets upon exercise. The warrant liabilities, which consisted of warrants for the purchase of Series B convertible preferred stock, were initially recorded at fair value upon the date of issuance of each warrant and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liabilities were recognized as a component of other (expense) income in the consolidated statements of operations. Fair value of the preferred stock warrant liabilities were remeasured through the July 16, 2021 closing date on the consolidated statements of operations until the liability was reclassified to equity on the closing date.

### ***Leases***

In accordance with ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02" or "ASC 842"), the Company classifies leases at the lease commencement date. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the circumstances present. Leases with a term greater than one year will be recognized on the consolidated balance sheets as right-of-use assets ("ROU"), lease liabilities, and if applicable, long-term lease liabilities. The Company includes renewal options to extend the lease in the lease term where it is reasonably certain that it will exercise these options. Lease liabilities and the corresponding ROU are recorded based on the present values of lease payments over the terms. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rates, which are the rates that would be incurred to borrow on a collateralized basis, over similar terms, amounts equal to the lease payments in a similar economic environment. Variable payments that do not depend on a rate or index are not included in the lease liability and are recognized as incurred. Lease contracts do not include residual value guarantees nor do they include restrictions or other covenants. Certain adjustments to ROUs may be required for items such as initial direct costs paid, incentives received, or lease prepayments. If significant events, changes in



circumstances, or other events indicate that the lease term or other inputs have changed, the Company would reassess lease classification, remeasure the lease liability using revised inputs as of the reassessment date, and adjust the ROU.

The Company has elected the “package of 3” practical expedients permitted under the transition guidance, which eliminates the requirements to reassess prior conclusions about lease identification, lease classification, and initial direct costs. The Company also adopted an accounting policy which provides that leases with an initial term of 12 months or less and no purchase option that the Company is reasonably certain of exercising will not be included within the lease right-of-use assets and lease liabilities on its consolidated balance sheets.

Refer to Note 11 for further information.

### ***Short-Term Debt***

We elected the fair value option to account for the financial instrument as per the pre-paid advance agreement with Yorkville. The estimate of the fair value was determined using a binomial lattice model. The fair value measurement of the debt is determined using Level 3 inputs and assumptions unobservable in the market. Changes in the fair value of debt that is accounted for at fair value, inclusive of related accrued interest expense, are presented as gains or losses in the accompanying consolidated statements of operations and comprehensive loss under change in fair value of debt. The portion of total changes in fair value of debt attributable to changes in instrument-specific credit risk are determined through specific measurement of periodic changes in the discount rate assumption exclusive of base market changes and are presented as a component of comprehensive income (loss) in the accompanying consolidated statements of operations and comprehensive loss. The actual settlement of the short-term debt could differ from current estimates based on the timing of when and if Yorkville elects to convert amounts into common shares, potential cash repayment by us prior to maturity, and movements in our common share price.

### ***Revenue Recognition***

The Company generates revenue from its degenerative disease commercial operations (i.e., the sale of Biovance®, Interfyl®), biobanking services (i.e., the collection, processing and storage of umbilical cord and placental blood and tissue after full-term pregnancies), and license, royalty and other revenues.

#### **Product sales and rentals**

Biovance® is a decellularized, dehydrated human amniotic membrane with a preserved natural epithelial basement membrane and an intact extracellular matrix structure with its biochemical components, and is intended for use as a biological membrane covering that provides the extracellular matrix while supporting the repair of damaged tissue. Interfyl® is an allogeneic decellularized particulate human placental connective tissue matrix consisting of natural human structural and biochemical extracellular matrix components and is intended for use in both surgical requirements and wound care as the replacement or supplementation of damaged or inadequate integumental tissue.

The Company recognizes revenue when control of the products and services is transferred to its customers in an amount that reflects the consideration it expects to receive from its customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when, or as, the performance obligations have been satisfied. Sales and other taxes collected on behalf of third parties are excluded from revenue.

A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. Transaction prices of products or services are typically based on contracted rates with customers and to the extent that the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value method or the most likely amount, depending on the circumstances, to which the Company expects to be entitled.

The Company offers volume-based discounts, rebates and prompt pay discounts and other various incentives which are accounted for under the variable consideration model. If sales incentives may be earned by a customer for purchasing a specified amount of product, the Company estimates whether such incentives will be achieved and recognizes these incentives as a reduction in revenue in the same period the underlying revenue transaction is recognized. The Company primarily uses the expected value method to estimate incentives. Under the expected value method, the Company considers the historical experience of similar programs as well as reviews sales trends on a customer-by-customer basis to estimate what levels of incentives will be earned.

The Company provides for rights of return to customers on its degenerative disease products. To date, the Company has had minimal product returns and therefore does not record a provision for returns. The Company offers product warranties which provide assurance that the product will function as expected and in accordance with specification. Customers can purchase warranties separately and these warranties give rise to a separate performance obligation.

### Services

The Company recognizes revenue separately for biobanking collection and processing services and storage services. Processing and storage services include the Company providing umbilical cord blood, placental blood and tissue processing and storage for private use. Revenues recognized for the fees for processing and storage represent sales of the biobanking to customers. The Company recognizes revenue from processing fees at the point in time of the successful completion of processing and recognizes storage fees over time, which is ratably over the contractual storage period. Contracted storage periods are generally 18 years and 25 years. Deferred revenue on the accompanying consolidated balance sheets includes the portion of the 18- and the 25-year storage fees that are being recognized over the contractual storage period. The Company classifies deferred revenue as current if the Company expects to recognize the related revenue over the next 12 months from the balance sheet date.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. For all plans (annual, lifetime, 18 years and 25 years), the storage fee is paid at the beginning of the storage period (prepaid plans). Alternatively, the Company offers payment plans for customers to pay over time for a period of one to 24 months (over time plans). The Company concluded that a significant financing component is not present within either the prepaid or overtime payment plans. The Company has determined that the prepaid plans do not include a significant financing component as the payment terms were structured primarily for reasons other than the provision of financing and to maximize profitability.

When considered over a 24-month period for over time plans, the difference between the cash selling price and the consideration paid is nominal. As such, the Company believes that its payment plans do not include significant financing components as they are not significant in the aggregate when considered in the context of all contracts entered into nor significant at the individual contract level.

The Company offers promotional discounts and other various incentives which are accounted for under the variable consideration model. The Company estimates whether such incentives will be achieved and recognizes these incentives as a reduction in revenue in the same period the underlying revenue transaction is recognized. The Company primarily uses the expected value method to estimate incentives. Under the expected value method, the Company considers the historical experience of similar programs as well as reviews sales trends on a customer-by-customer basis to estimate what levels of incentives will be earned.

As the Company's processing and storage agreements contain multiple performance obligations, ASC 606 *Revenue from Contracts with Customers*, requires an allocation of the transaction price based on the estimated relative standalone selling prices of the promised services underlying each performance obligation. The Company has selected an adjusted market assessment approach to estimate the standalone selling prices of the processing services and storage services and concluded that the published list price is the price that a customer in that market would be willing to pay for those goods or services. The Company also considered the fact that all customers are charged the list prices current at the time of their enrollment where the Company has separately stated list prices for processing and storage.

### License, royalty and other

Under license agreements, the Company assesses whether the related performance obligation is satisfied at a point in time or over time.

Under the license agreement with Sanuwave Health Inc. ("Sanuwave") which acquired certain assets comprising its MIST®/UltraMIST® business (see Note 16), the Company received a quarterly license fee and a defined royalty on each product sold. A credit was provided to Sanuwave for Biovance royalties up to the quarterly license fee. The Company recognized the quarterly license fee over each quarterly term based on the actual sales occurring over the period. The license agreement with Sanuwave was terminated during the third quarter of 2021 due to an uncured material breach.

At the inception of each arrangement that includes milestone payments based on certain events, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to

constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. If a milestone or other variable consideration relates specifically to the Company's efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, the Company generally allocates the milestone amount entirely to that performance obligation once it is probable that a significant revenue reversal would not occur. See Note 16 for further discussion of the Company's license agreements.

While the Company's direct sales of degenerative disease products are included in product sales and rentals, sales through the Company's network of distribution partners are included in license, royalty and other revenues. For certain distribution agreements as described in Note 16, the Company will utilize the practical expedient in ASC 606-10-55-83, whereby an entity may recognize revenue in the amount to which the entity has a right to invoice so long as the consideration from a customer corresponds directly with the value received. Thus, the Company will recognize revenue upon invoicing for these agreements (subsequent to receipt of the related purchase order).

### ***Cost of Revenues***

Cost of revenues consists of labor, material and overhead costs associated with the Company's two existing commercial business segments, biobanking and degenerative disease. Biobanking costs include the cost of storage and transportation kits for newly banked materials as well as tank and facility overhead costs for cord blood and other units in storage. Degenerative disease costs include costs associated with procuring placentas, qualifying the placental material and processing the placental tissue into a marketable product. Costs in the degenerative disease segment include labor and overhead costs associated with the production of the Biovance, Biovance 3L and Interfyl product lines. During the year ended December 31, 2022, the Company incurred significant cost to ramp up production in anticipation of degenerative disease sales with distribution partners that did not materialize. These costs were included in cost of revenues and resulted in cost of revenues higher than revenue for distribution partners included in License, royalty and other.

### ***Research and Development Costs***

The Company has entered into various research and development and other agreements with commercial firms, researchers, universities and others for provisions of goods and services. These agreements are generally cancellable, and the related costs are recorded as research and development expense as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility-related expenses, depreciation and amortization, stock-based compensation, third-party license fees, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, preclinical and clinical development activities and clinical trials as well as to manufacture clinical trial materials, and other costs. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Upfront payments, milestone payments and annual maintenance fees under license agreements are expensed in the period in which they are incurred.

### ***Advertising and Marketing Costs***

Advertising and marketing costs are expensed as incurred. Advertising and marketing costs are included in selling, general and administrative expenses and were \$163 and \$252 for the years ended December 31, 2022 and 2021, respectively.

### ***Government Grants***

From time to time, the Company may be awarded a government research grant. Under these arrangements, the Company recognizes awarded grants as a reduction to research and development expense at the point in time where achievement of related milestones is confirmed by the governmental agency. The Company did not receive grant monies during the years ended December 31, 2022 and 2021.

### ***Patent Costs***

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified in selling, general and administrative expenses.

## ***Stock-Based Compensation***

The Company measures all stock-based awards granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense for those awards, over the requisite service period, which is generally the vesting period of the respective award. The Company typically issues stock-based awards with only service-based vesting conditions and records the expense for these awards using a straight-line method.

The Company's board of directors may also approve and award performance-based stock options. The performance-based stock options are earned based on the attainment of specified goals achieved over the performance period. The Company recognizes expense for performance-based awards over the related vesting period once it deems the achievement of the performance condition is probable. The Company reassesses the probability of vesting at each reporting period for performance-based awards and adjusts expense accordingly on a cumulative basis.

The fair value of each services and performance-based stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information for its stock. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options granted to employees is determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employee consultants is equal to the contractual term of the option award or our estimated term based on the underlying agreement. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is zero based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

In September 2021, the Company awarded options to its former President which had market-based vesting conditions. The Company used the Monte-Carlo model in order to calculate the fair value of the market-based awards. Also in 2021, the Company granted restricted stock units ("RSUs"), the fair value of which is determined based on the stock price on the date of grant (see Note 14).

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified. The Company elects to account for forfeitures as they occur and compensation cost previously recognized for an award that is forfeited because of a failure to satisfy a service or performance condition is generally reversed in the period of the forfeiture.

## ***Comprehensive Income (Loss)***

Comprehensive income (loss) refers to revenues, expenses, gains and losses that under U.S. GAAP are included in comprehensive income (loss) but are excluded from net income (loss) as these amounts are recorded directly as an adjustment to accumulated other comprehensive income (loss). The Company's only component of other comprehensive income (loss) is comprised of the portion of the total change in fair value of indebtedness accounted for under the fair value option that is attributable to changes in instrument-specific credit risk. During the year ended December 31, 2022, the Company recorded instrument-specific credit risk income of \$20 and \$11 was reclassified from accumulated other comprehensive income to other income upon short-term debt conversion. These amounts have been recorded as a separate component of stockholders' equity (deficit).

## ***Income Taxes***

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained based on the technical merits of the position. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate

settlement with the tax authority. The provision for income taxes includes the effects of unrecognized tax benefits, as well as the related interest and penalties (see Note 18).

### ***Net Income (Loss) per Share***

Basic net income (loss) per share of common stock is computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding during each period. Diluted net income (loss) per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible debt, stock options, restricted stock units and warrants, which would result in the issuance of incremental shares of common stock. However, potential common shares are excluded if their effect is anti-dilutive. For diluted net income (loss) per share, the weighted-average number of shares of common stock is the same for basic net income (loss) per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. For the year ended December 31, 2022, the Company was in a net income position and calculated the diluted net income per share by dividing the Company's net income by the dilutive weighted average number of shares outstanding during the year, determined using the treasury stock method. A reconciliation of the numerators and denominators of the basic and diluted net income (loss) per share calculations are as follows:

	Year Ended December 31,	
	2022	2021
Numerator:		
Net income (loss)	\$ 14,192	\$ (100,118)
Denominator:		
Weighted average shares outstanding, basic	139,907,029	67,057,278
Weighted average dilutive stock options	9,586,018	—
Weighted average restricted stock units	336,969	—
Weighted average shares outstanding, diluted	149,830,016	67,057,278
Net income (loss), basic	\$ 0.10	\$ (1.49)
Net income (loss), diluted	\$ 0.09	\$ (1.49)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, prior to the use of the two-class method, as they would be anti-dilutive:

	December 31,	
	2022	2021
Stock options	12,392,188	26,533,868
Restricted stock units	1,284,090	474,700
Warrants	33,458,360	42,686,195
Convertible debt	6,291,011	—
	53,425,649	69,694,763

### ***Segment Information***

Operating segments are defined as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources in assessing performance. The Company manages its operations through an evaluation of three distinct businesses segments: Cell Therapy, Degenerative Disease and BioBanking. These segments are presented for the years ended December 31, 2022 and 2021 in Note 19.

### ***Concentrations of Credit Risk and Significant Customers***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents and restricted cash. The Company generally maintains balances in various operating accounts at financial institutions that management believes to be of high credit quality, in amounts that may exceed federally insured limits. The Company has not experienced any losses related to its cash and cash equivalents or restricted cash and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is subject to credit risk from trade accounts receivable related to both degenerative disease product sales and biobanking services. All trade accounts receivables are a result from product sales and services performed in the United States. As of December 31, 2022, one of the Company's customers (Customer A) comprised 38% of the Company's outstanding gross accounts receivable, and two other customers comprised 33% of the outstanding gross accounts receivable. As of December 31, 2021, Customer A comprised of 44% of the Company's outstanding gross accounts receivable, and one other customer comprised 12% of the outstanding



gross accounts receivable. During the year ended December 31, 2022, the Company had two customers provide for 37% of revenue and Customer A provided for 11% of revenue. During the year ended December 31, 2021, the Company had one customer provide for 38% of revenue and Customer A provided for 11% of revenue.

In November 2017, the FDA provided guidance that established an updated framework for regulation of Human Cell & Tissue Products (“HCT/P”). The Company’s Interfyl products meet the criteria for minimal manipulation and homologous use as outlined within the applicable guidance and has an official designation from the FDA as an HCT/P product. As a result, the Company did not stop selling its Interfyl products when the FDA ended its enforcement discretion on May 31, 2021. However, the Center for Medicare and Medicaid Services (“CMS”) began rejecting claims for Interfyl submitted by Customer A. The Company believes that CMS is not distinguishing the Interfyl products from its competitors’ products. While the Company and Customer A continue to work with CMS to resolve the rejected claims, a reserve of \$1,762 was recorded on Customer A’s accounts receivable balance as of December 31, 2022.

### ***Emerging Growth Company***

Section 102(b)(1) of the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”) exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act of 1933, as amended, registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard.

This may make comparison of the Company’s financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

### ***Reclassifications***

Certain prior period amounts have been reclassified to conform with current year presentation.

### ***Recently Adopted Accounting Pronouncements***

On January 1, 2022, the Company adopted ASU 2016-02, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a ROU asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to the prior guidance for operating leases.

The Company adopted ASU 2016-02 utilizing the modified retrospective transition method in the first quarter of fiscal 2022 and did not restate comparative periods. The Company has elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed it to carry forward the historical lease classification. Refer to Note 11 for further information on the impact of the adoption of ASU 2016-02 on the Company’s consolidated financial statements.

Upon adoption, the Company recorded ROU assets and lease liabilities of \$13,001 and \$27,723, respectively, on the consolidated balance sheets. Incremental borrowing rates as of January 1, 2022, the date the new standard was adopted, were used to calculate the present value of the Company’s lease portfolio as of that date. Leases previously identified as build-to-suit leases were derecognized pursuant to the transition guidance provided for build-to-suit leases in ASU 2016-02. The impact of the derecognition of the build-to-suit lease was a net reduction of \$3,993 to accumulated deficit calculated as of January 1, 2022. The standard did not materially impact the consolidated net income (losses) or operating cash flows.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260)*, *Debt - Modifications and Extinguishments (Subtopic 470-50)*, *Compensation - Stock Compensation (Topic 718)*, and *Derivatives and Hedging - Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* (“ASU 2021-04”). ASU 2021-04 provides guidance as to how an issuer should account for a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option (i.e., a warrant) that remains equity-classified after modification or exchange as an exchange of the original instrument for a new instrument. An issuer should measure the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately

before modification or exchange and then apply a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). The Company adopted ASU 2021-04 effective January 1, 2022 and considered this guidance when evaluating the amendment of the Company's warrants in March 2022 (See Note 13.)

In November 2021, the Financial Accounting Standards Board ("FASB") issued ASU 2021-10, "Government Assistance (Topic 832)", which provides disclosure requirements regarding government grants and contributions. The ASU requires disclosure of the nature of transactions and related accounting policies used to account for transactions, the effect, including amounts, of government assistance on individual line items on the financial statements, and significant terms and conditions of the transactions, including commitments and contingencies. This ASU is effective for fiscal years beginning after December 15, 2021. The Company adopted the provisions of this ASU effective January 1, 2022. There was no impact upon adoption.

In August 2020, the FASB issued ASU 2020-06, (Subtopic 470-20): *Debt — Debt with Conversion and Other Options* ("ASU 2020-06") to address the complexity associated with applying GAAP to certain financial instruments with characteristics of liabilities and equity. ASU 2020-06 includes amendments to the guidance on convertible instruments and the derivative scope exception for contracts in an entity's own equity and simplifies the accounting for convertible instruments which include beneficial conversion features or cash conversion features by removing certain separation models in Subtopic 470-20. Additionally, ASU 2020-06 requires entities to use the "if-converted" method when calculating diluted earnings per share for convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023 (fiscal year 2024 for the Company), including interim periods within those fiscal years with early adoption permitted. The Company early adopted ASU 2020-06 effective January 1, 2022 and considered this guidance when evaluating the warrants issued in May 2022 (See Note 13), and when calculating diluted earnings per share above.

### ***Recently Issued Accounting Pronouncements***

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments — Credit Losses* ("ASU 2016-13"), which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. ASU 2016-13 also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. ASU 2016-13 is effective for annual periods beginning after December 15, 2022 (fiscal year 2023 for the Company), and interim periods within those periods, with early adoption permitted. The Company adopted ASU 2016-13 effective January 1, 2023. The standard did not have a material impact on the consolidated financial statements.

### **3. Business Combinations**

On July 16, 2021, the Company consummated the previously announced merger pursuant to the Merger Agreement, by and among GX, First Merger Sub, Second Merger Sub and Legacy Celularity (see Note 1).

Pursuant to the terms of the Merger Agreement, a business combination between GX and Legacy Celularity was effected through the (a) merger of First Merger Sub with and into Legacy Celularity with Legacy Celularity surviving as a wholly-owned subsidiary of GX (Legacy Celularity, in its capacity as the surviving corporation of the merger, the "Surviving Corporation") (the "First Merger") and (b) immediately following the First Merger and as part of the same overall transaction as the First Merger, the merger of the Surviving Corporation with and into Second Merger Sub, with Second Merger Sub as the surviving entity of the Second Merger, which ultimately resulted in Legacy Celularity becoming a wholly-owned direct subsidiary of GX (the "Second Merger" and, together with the First Merger, the "Mergers" and, collectively with the other transactions described in the Merger Agreement, the "Business Combination"). On the Closing Date, the Company changed its name from GX Acquisition Corp. to Celularity Inc.

Immediately prior to the effective time of the Mergers (the "Effective Time"), each share of preferred stock of Legacy Celularity (the "Legacy Celularity Preferred Stock") that was issued and outstanding was automatically converted into a number of shares of common stock of Legacy Celularity, par value \$0.0001 per share (the "Legacy Celularity Common Stock") at the then-effective conversion rate as calculated pursuant to the Amended and Restated Certificate of Incorporation of Legacy Celularity, dated March 16, 2020, as amended (the "Legacy Celularity Charter"), such that each converted share of Legacy Celularity Preferred Stock was no longer outstanding and ceased to exist, and each holder of Legacy Celularity Preferred Stock thereafter ceased to have any rights with respect to such securities (the "Legacy Celularity Preferred Stock Conversion").

At the Effective Time, by virtue of the First Merger and without any action on the part of GX, First Merger Sub, Legacy Celularity or the holders of any of the following securities:

- a. each share of Legacy Celularity Common Stock (including shares of Legacy Celularity Common Stock resulting from the conversion of shares of Celularity Preferred Stock described above) that was issued and outstanding immediately prior to the Effective Time was cancelled and converted into the right to receive a number of shares of Company Class A common stock, par value \$0.0001 per share (the "Class A Common Stock" or "Common Stock") equal to the Exchange Ratio (as defined below) (the "Per Share Merger Consideration");

- b. each share of Legacy Celularity Common Stock or Legacy Celularity Preferred Stock (together, “Legacy Celularity Capital Stock”) held in the treasury of Celularity was cancelled without any conversion thereof and no payment or distribution was made with respect thereto;
- c. each share of First Merger Sub common stock, par value \$0.01 per share, issued and outstanding immediately prior to the Effective Time was converted into and exchanged for one validly issued, fully paid and nonassessable share of common stock, par value \$0.0001 per share, of the Surviving Corporation;
- d. each Legacy Celularity Warrant (as to which no notice of exercise had been delivered to Legacy Celularity prior to the Closing) that was outstanding immediately prior to the Effective Time (and which would have otherwise been exercisable in accordance with its terms immediately following the Effective Time), became, to the extent consistent with the terms of such Legacy Celularity Warrant, the right to purchase shares of Class A Common Stock (and not Celularity Capital Stock) (each, a “Converted Warrant”) on the same terms and conditions (including exercisability terms) as were applicable to such Legacy Celularity Warrant immediately prior to the Effective Time, except that (A) each Converted Warrant became exercisable for that number of shares of Class A Common Stock equal to the product (rounded down to the nearest whole number) of (1) the number of shares of Legacy Celularity Common Stock that would have been issuable upon the exercise of a Legacy Celularity Warrant for cash and assuming the conversion of the Series B Preferred Stock underlying such outstanding Legacy Celularity Warrant into Legacy Celularity Common Stock (the “Celularity Warrant Shares”) subject to the Legacy Celularity Warrant immediately prior to the Effective Time and (2) the Exchange Ratio (as defined below); and (B) the per share exercise price for each share of Class A Common Stock issuable upon exercise of the Converted Warrant is equal to the quotient (rounded up to the nearest whole cent) obtained by dividing (1) the per share exercise price for each share of Series B Preferred Stock issuable upon exercise of such Celularity Warrant immediately prior to the Effective Time by (2) the Exchange Ratio (as defined below); and
- e. each option to purchase Legacy Celularity Common Stock, whether or not exercisable and whether or not vested, that was outstanding immediately prior to the Effective Time (each, a “Legacy Celularity Option”) was assumed by GX and converted into an option to purchase shares of Class A Common Stock (each, a “Converted Option”).

The Business Combination was accounted for as a reverse recapitalization in conformity with accounting principles generally accepted in the United States. Under this method of accounting, GX was treated as the “acquired” company for financial reporting purposes. This determination was primarily based on existing Legacy Celularity stockholders comprising a relative majority of the voting power of the combined company, Legacy Celularity’s operations prior to the acquisition comprising the only ongoing operations of Celularity, the majority of Celularity’s board of directors appointment by Legacy Celularity, and Legacy Celularity’s senior management comprising a majority of the senior management of Celularity. Accordingly, for accounting purposes, the financial statements of the combined entity represented a continuation of the financial statements of Legacy Celularity with the business combination being treated as the equivalent of Legacy Celularity issuing stock for the net assets of GX, accompanied by a recapitalization. The Company recorded the net assets of GX at historical costs, with no goodwill or other intangible assets recorded. Operations prior to the business combination are those of Legacy Celularity. Reported shares and earnings (losses) per share available to holders of the Class A Common Stock, prior to the Business Combination, have been retroactively restated as shares reflecting the exchange ratio established in the business combination (1.00 share of Legacy Celularity for approximately 0.7686 shares of Class A Common Stock).

Net proceeds from this transaction totaled \$108,786. These proceeds were comprised of \$5,386 held in GX’s trust account, \$83,400 received from the completion of a concurrent private investment in public equity financing (“July 2021 PIPE Financing”) and \$20,000 received from an investment by Palantir Technologies, Inc. (“Palantir”). The Company incurred \$21,658 in transaction costs relating to the merger with GX of which \$10,795 were satisfied by the issuance of Class A Common Stock, which has been offset against additional paid-in capital in the consolidated statements of convertible preferred stock and stockholders’ equity (deficit).

Pursuant to the terms of the Merger Agreement, the existing stockholders of Legacy Celularity exchanged their interests for shares of Class A Common Stock. In addition, GX had previously issued public warrants and private placement warrants (collectively, the “GX Warrants”) as part of the Units in its IPO in May 2019. None of the terms of the GX Warrants were modified as a result of the Business Combination. On the date of the Business Combination, the Company recorded a liability related to the GX Warrants of \$59,202, with an offsetting entry to additional paid-in capital. During the year ended December 31, 2022, and during the period from July 17, 2021 to December 31, 2021, the fair value of the GX Warrants decreased to \$2,196 and \$25,962, respectively, resulting in other income of \$23,766 and \$33,240, respectively, in the consolidated statements of operations for the years ended December 31, 2022 and 2021.

Upon consummation of the Business Combination, Legacy Celularity warrants qualified for equity classification. As a result, the transaction date fair value of the Legacy Celularity warrants of \$96,398 was reclassified from warrant liability to additional paid-in capital (see Note 13).

Immediately following the Business Combination, there were 122,487,174 shares of Class A Common Stock with a par value of \$0.0001 issued and outstanding, options to purchase an aggregate of 21,723,273 shares of Class A Common Stock and 42,686,195 warrants outstanding to purchase shares of Class A Common Stock.

#### *July 2021 PIPE Financing (Private Placement)*

On the Closing Date, certain significant stockholders of Legacy Celularity or their affiliates (including Sorrento Therapeutics, Inc., Starr International Investments Ltd. and Dragasac Limited, an indirect wholly owned subsidiary of Genting Berhad, collectively, the “Subscribers”) purchased from Celularity an aggregate of 8,340,000 shares of Class A Common Stock (the “July 2021 PIPE Shares”), for a purchase price of \$10.00 per share and an aggregate purchase price of \$83,400, pursuant to separate subscription agreements dated January 8, 2021 (collectively, the “Subscription Agreements”). Pursuant to the Subscription Agreements, the Company agreed to provide the Subscribers with certain registration rights with respect to the July 2021 PIPE Shares.

#### *Arrangement with Palantir Technologies Inc.*

Pursuant to the subscription agreement entered into by GX with Palantir on May 5, 2021, Palantir purchased 2,000,000 shares of Class A Common Stock at a price of \$10.00 per share and an aggregate purchase price of \$20,000, upon closing of the Business Combination and closing of the PIPE financing.

#### **4. Fair Value of Financial Assets and Liabilities**

The following tables present information about the Company’s financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Fair Value Measurements as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents - money market funds	\$ 12,174	\$ —	\$ —	\$ 12,174
Convertible note receivable	—	—	2,514	2,514
	<u>\$ 12,174</u>	<u>\$ —</u>	<u>\$ 2,514</u>	<u>\$ 14,688</u>
<b>Liabilities:</b>				
Acquisition-related contingent consideration obligations	\$ —	\$ —	\$ 105,945	\$ 105,945
Contingent stock consideration	—	—	186	186
Short-term debt - Yorkville	—	—	37,603	37,603
Warrant liability - May 2022 PIPE Warrants	—	—	1,402	1,402
Warrant liability - Sponsor Warrants	—	—	1,190	1,190
Warrant liability - Public Warrants	1,006	—	—	1,006
	<u>\$ 1,006</u>	<u>\$ —</u>	<u>\$ 146,326</u>	<u>\$ 147,332</u>
<b>Fair Value Measurements as of December 31, 2021</b>				
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents – money market funds	\$ 36,700	\$ —	\$ —	\$ 36,700
Convertible note receivable	—	—	2,488	2,488
	<u>\$ 36,700</u>	<u>\$ —</u>	<u>\$ 2,488</u>	<u>\$ 39,188</u>
<b>Liabilities:</b>				
Acquisition-related contingent consideration obligations	\$ —	\$ —	\$ 232,222	\$ 232,222
Warrant liability - Sponsor Warrants	—	—	13,600	13,600
Warrant liability - Public Warrants	12,362	—	—	12,362
	<u>\$ 12,362</u>	<u>\$ —</u>	<u>\$ 245,822</u>	<u>\$ 258,184</u>

During the years ended December 31, 2022 and 2021, there were no transfers between Level 1, Level 2 and Level 3.

The Company’s cash equivalents consisted of a money market funds. The money market fund was valued using inputs observable in active markets for similar securities, which represents a Level 1 measurement in the fair value hierarchy. The carrying values of accounts receivable, accounts payable, deferred revenue and other current liabilities approximate fair value in the accompanying consolidated financial statements due to the short-term nature of those instruments.



### Valuation of Contingent Consideration

The fair value measurement of the contingent consideration obligations is determined using Level 3 inputs and is based on a probability-weighted income approach. The measurement is based upon unobservable inputs supported by little or no market activity based on the Company's own assumptions.

The following table presents a reconciliation of contingent consideration obligations measured on a recurring basis using Level 3 inputs as of December 31, 2022 and 2021:

	Balance as of December 31, 2021	Net transfers in to (out of) Level 3	Purchases, settlements and other net	Fair value adjustments	Balance as of December 31, 2022
<b>Liabilities:</b>					
Acquisition-related contingent consideration obligations	\$ 232,222	\$ —	\$ —	\$ (126,277)	\$ 105,945
	Balance as of December 31, 2020	Net transfers in to (out of) Level 3	Purchases, settlements and other net	Fair value adjustments	Balance as of December 31, 2021
<b>Liabilities:</b>					
Acquisition-related contingent consideration obligations	\$ 273,367	\$ —	\$ —	\$ (41,145)	\$ 232,222

The fair value of the liability to make potential future milestone and earn-out payments was estimated by the Company at each reporting date based, in part, on the results of a third-party valuation using a discounted cash flow analysis based on various assumptions, including the probability of achieving specified events, discount rates, and the period of time until earn-out payments are payable and the conditions triggering the milestone payments are met. The actual settlement of contingent consideration could differ from current estimates based on the actual occurrence of these specified events.

At each reporting date, the Company revalues the contingent consideration obligation to estimated fair value and records changes in fair value as income or expense in the Company's consolidated statements of operations. Changes in the fair value of the contingent consideration obligations may result from changes in discount periods and rates, changes in the timing and amount of revenue estimates and changes in probability assumptions with respect to the likelihood of achieving the various contingent consideration obligations. The Company has classified all of the contingent consideration as a long-term liability in the consolidated balance sheets as of December 31, 2022 and 2021. See Note 12, "Commitment and Contingencies", for more information on contingent consideration.

### Valuation of Warrant Liability

The warrant liability at December 31, 2022 is composed of the fair value of warrants to purchase shares of Class A Common Stock. The private placement warrants assumed upon the Business Combination (the "Sponsor Warrants") and the May 2022 PIPE Warrants (see Note 13) were recorded at their respective closing date fair values based on a Black-Scholes option pricing model that utilizes inputs for: (i) value of the underlying asset, (ii) the exercise price, (iii) the risk-free rate, (iv) the volatility of the underlying asset, (v) the dividend yield of the underlying asset and (vi) maturity. The Black-Scholes option pricing model's primary unobservable input utilized in determining the fair value of the Sponsor Warrants and May 2022 Pipe Warrants is the expected volatility of the Class A Common Stock. Prior to the Mergers, Legacy Celularity was historically a private company and lacks company-specific historical and implied volatility information for its stock. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies. Inputs to the Black-Scholes option pricing model for the warrants are updated each reporting period to reflect fair value. The public warrants assumed upon the Business Combination (the "Public Warrants") were recorded at the closing date fair value based on the close price of such warrants. Each subsequent reporting period, the Public Warrants are marked-to-market based on the period-end close price.

As of December 31, 2022 and 2021, the fair value of the warrant liabilities was \$3,598 and \$25,962, respectively. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the estimated remaining term of the warrants.



The following table provides a roll-forward of the aggregate fair values of the Company's warrant liabilities for which fair values are determined using Level 3 inputs:

Balance as of December 31, 2020	\$	76,640
Gain recognized in earnings from change in fair value		(13,482)
Warrant liability assumed at Closing Date (Sponsor Warrants)		34,764
Warrant liability assumed at Closing Date (Public Warrants)		24,438
Reclassification of Legacy Celularity Warrants to equity		(96,398)
Balance as of December 31, 2021	\$	<u>25,962</u>
Balance as of December 31, 2021	\$	25,962
May 2022 PIPE warrant issuance		19,745
Gain recognized in earnings from change in fair value		(42,109)
Balance as of December 31, 2022	\$	<u>3,598</u>

The fair value of the Public Warrants was \$1,006 and \$12,362 as of December 31, 2022 and 2021, respectively, based on the publicly stated closing price. The fair value of the Sponsor Warrants was \$1,190 and \$13,600 as of December 31, 2022 and 2021, respectively. The fair value of the May 2022 PIPE Warrants was \$1,402 as of December 31, 2022.

Significant inputs for the Sponsor Warrants are as follows:

	December 31, 2022	December 31, 2021
Common share price	\$ 1.29	\$ 5.12
Exercise price	\$ 11.50	\$ 11.50
Dividend yield	0%	0%
Term (years)	3.5	4.5
Risk-free interest rate	4.16%	1.19%
Volatility	75.0%	63.0%

Significant inputs for the May 2022 PIPE Warrants are as follows:

	December 31, 2022
Common share price	\$ 1.29
Exercise price	\$ 8.25
Dividend yield	0%
Term (years)	4.4
Risk-free interest rate	3.99%
Volatility	81.2%

The Company used a lattice model to value the Legacy Celularity warrants issued as the exercise price was a function of the stock price. In the application of each model, estimates and assumptions impacting the fair value measurement included the fair value per share of the underlying shares of Legacy Celularity's Series B convertible preferred stock, risk-free interest rate, and exercise date with considerations of the earlier of when the investor was required to exercise and the anticipated exit date. The most significant assumption in the forward contract model impacting the fair value of the preferred stock warrants was the fair value of Legacy Celularity's convertible preferred stock as of each remeasurement date. The Company determined the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of Legacy Celularity's convertible preferred stock, results obtained from third-party valuations and additional factors that are deemed relevant.

The fair value of the warrants issued to Dragasac was \$33,435 as of July 16, 2021. On the Closing Date, the Dragasac warrants qualified for equity classification and were reclassified accordingly. Significant inputs for the warrants issued to Dragasac are as follows:

	July 16, 2021
Fair value of common stock	\$ 9.66 - 10.20
Exercise price <sup>a</sup>	\$ 6.77
Term (years)	3.67
Risk-free interest rate	0.60%
Volatility	54.0%

- (a) The exercise price is the lower of \$6.77 per share or 80% of either (i) the value attributed to one share of Legacy Celularity Series B Preferred Stock upon a consummation of a change of control or the closing of a strategic transaction or (ii) the price at which

one share of Legacy Celularity common stock is sold to the public in an initial public offering. As amended on March 16, 2020, the warrants are exercisable on the first to occur of (a) March 16, 2025, (b) the consummation of Legacy Celularity's initial public offering, (c) the consummation of a change of control and (d) the closing of a strategic transaction pursuant to which Legacy Celularity's stockholders exchange their existing shares of capital stock in Legacy Celularity for shares in a company whose shares are listed on a national stock exchange.

The fair value of the warrants issued in connection with the Legacy Celularity Series B Preferred Stock was \$62,963 as of July 16, 2021. On the Closing Date, these warrants qualified for equity classification and were reclassified accordingly. Significant inputs for the warrants issued in connection with the Legacy Celularity Series B Preferred Stock are as follows:

		July 16, 2021
Fair value of common stock	\$	9.66 - 10.20
Exercise price <sup>b</sup>	\$	7.53
Term		3.67
Risk-free interest rate		0.60%
Volatility		54.0%

- (b) The warrants are exercisable at a price of \$7.53 per share on the first to occur of: (a) the 60-month anniversary of the date of issuance of the warrants, (b) the consummation of an agreement for a public exit event, and (c) the consummation of a change of control.

#### ***Valuation of the Convertible Note Receivable***

The convertible note receivable was received in connection with the disposition of the UltraMIST/MIST business in 2020. At any time on or after January 1, 2021, at the sole discretion of the Company, amounts outstanding under the convertible note receivable (including accrued interest) may be converted into Sanuwave common stock at a defined rate. The convertible promissory note was to be paid on or before August 6, 2021, however, remains outstanding in full as of December 31, 2022 and 2021. The fair value of this note was based on a bond valuation which employs a credit default model. The Company utilized Level 3 inputs on a probability weighted model based on outcomes of a default, repayment and conversion of the note. The measurement is based upon unobservable inputs supported by little or no market activity based on the Company's own assumptions.

Significant inputs for the convertible note valuation model are as follows:

	December 31, 2022	December 31, 2021
Face value	\$ 4,000	\$ 4,000
Coupon rate	12% - 17%	12% - 17%
Stock price	\$ 0.02	\$ 0.17
Term (years)	1.01 - 3.45	.7 - 3.19
Risk-free interest rate	4.73%	0.29%
Volatility	n/a	n/a

#### ***Valuation of the Contingent Stock Consideration***

The contingent stock consideration liability at December 31, 2022, is comprised of the fair value of potential future issuance of Class A Common Stock to CariCord participating shareholders pursuant to a settlement agreement signed during the year ended December 31, 2021 (see Note 12). The fair value measurement of the contingent stock consideration obligation is determined using Level 3 inputs and is based on a probability-weighted expected return methodology ("PWERM"). The measurement is largely based upon unobservable inputs supported by little or no market activity based on the Company's own assumptions. As of December 31, 2021, the applicable procurement targets were not probable of being achieved.

The following table presents a reconciliation of the contingent stock consideration obligation measured on a recurring basis using Level 3 inputs as of December 31, 2022 and 2021:

	Balance as of December 31, 2021	Net transfers in to (out of) Level 3	Purchases, settlements and other net	Fair value adjustments	Balance as of December 31, 2022
<b>Liabilities:</b>					
Contingent stock consideration	\$ -	\$ —	\$ —	\$ 186	\$ 186

The fair value of the liability to issue future shares of Class A Common Stock was estimated by the Company at each reporting date using a PWERM based on various inputs and assumptions, including the Company's common share price, discount rates, and the

probability of achieving specified future operational targets. The actual settlement of contingent stock consideration could differ from current estimates based on the actual achievement of these specified targets and movements in the Company's common share price.

At each reporting date, the Company revalues the contingent stock consideration obligation to estimated fair value and records changes in fair value as income or expense in the Company's consolidated statements of operations. Changes in the fair value of the contingent stock consideration obligation may result from changes in discount rates, changes in the Company's common share price, and changes in probability assumptions with respect to the likelihood of achieving specified operational targets. The Company has classified all of the contingent stock consideration as a current liability in the consolidated balance sheets as of December 31, 2022. See Note 12, "Commitments and Contingencies", for more information on contingent stock consideration.

#### ***Valuation of Short-Term Debt - Yorkville***

The Company elected the fair value option to account for the financial instrument with Yorkville signed on September 15, 2022 (see Note 10). The estimate of the fair value was determined using a binomial lattice model. The fair value measurement of the debt is determined using Level 3 inputs and assumptions unobservable in the market. Changes in the fair value of debt that is accounted for at fair value, inclusive of related accrued interest expense, are presented as gains or losses in the accompanying consolidated statements of operations and comprehensive income (loss) under change in fair value of debt. The portion of total changes in fair value of debt attributable to changes in instrument-specific credit risk are determined through specific measurement of periodic changes in the discount rate assumption exclusive of base market changes and are presented as a component of comprehensive income (loss) in the accompanying consolidated statements of operations and comprehensive income (loss). The actual settlement of the short-term debt could differ from current estimates based on the timing of when and if Yorkville elects to convert amounts into common shares, potential cash repayment by the Company prior to maturity, and movements in the Company's common share price.

The following table presents a reconciliation of the Yorkville debt measured on a recurring basis using Level 3 inputs as of the initial valuation date of September 15, 2022 and as of December 31, 2022:

<b>Liabilities:</b>		
Balance as of September 15, 2022	\$	39,200
Conversion of debt into common shares		(4,099)
Fair value adjustment through earnings		2,522
Fair value adjustment through accumulated other comprehensive income		(20)
Balance as of December 31, 2022	\$	37,603

Significant inputs for the Yorkville short-term debt valuation model are as follows:

	<b>December 31, 2022</b>
Common share price	\$ 1.29
Credit spread	13.71%
Dividend yield	0%
Term (years)	0.71
Risk-free interest rate	4.75%
Volatility	45.0%
Discount yield	18.46%

## **5. Inventory**

The Company's major classes of inventories were as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Raw materials	\$ 7,719	\$ 2,359
Work in progress	12,381	5,902
Finished goods	9,256	4,057
Inventory, gross	29,356	12,318
Less: inventory reserves	(1,099)	(48)
Inventory, net	\$ 28,257	\$ 12,270
<b>Balance Sheet Classification:</b>		
Inventory	5,308	9,549
Inventory, net of current portion	22,949	2,721
	\$ 28,257	\$ 12,270

Inventory, net of current portion includes inventory expected to remain on-hand beyond one year from each balance sheet date presented.

## 6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2022	2021
Prepaid clinical expenses	\$ 5,836	\$ 3,269
Prepaid insurance expense	377	1,399
Other	1,049	2,410
	<u>\$ 7,262</u>	<u>\$ 7,078</u>

## 7. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2022	2021
Building <sup>(1)</sup>	\$ —	\$ 12,513
Leasehold improvements <sup>(2)</sup>	70,113	71,468
Laboratory and production equipment	14,433	11,395
Machinery, equipment and fixtures	7,780	7,974
Construction in progress	3,660	2,054
Property and equipment	95,986	105,404
Less: Accumulated depreciation and amortization <sup>(3)</sup>	(20,331)	(14,779)
Property and equipment, net	<u>\$ 75,655</u>	<u>\$ 90,625</u>

(1) Includes \$12,513 at December 31, 2021 under financing lease resulting from a failed sale leaseback (see Note 11).

(2) Includes \$70,959 at December 31, 2021 under financing lease resulting from a failed sale leaseback (see Note 11).

(3) Includes \$5,971 at December 31, 2021 under financing lease resulting from a failed sale leaseback (see Note 11).

Depreciation expense was \$7,243 and \$6,625 for the years ended December 31, 2022 and 2021 respectively.

## 8. Goodwill and Intangible Assets, Net

The Company performs its annual goodwill impairment test in the fourth quarter of every year for all of our reporting units, and more frequently if events or circumstances indicate a potential impairment. During the quarter ended December 31, 2022, management identified various qualitative and quantitative factors which collectively indicated a triggering event had occurred and performed an impairment test. Based on the results of the impairment analysis, the Degenerative Disease reporting unit had a carrying amount that exceeded its fair value due to lower forecasted sales and growth and it was determined that all of the goodwill for the Degenerative Disease reporting unit was impaired as of December 31, 2022.

The carrying values of goodwill assigned to the Company's reporting units are as follows:

	Cell Therapy	Degenerative Disease	Biobanking	Total
Balance at December 31, 2021	\$ 112,347	\$ 3,610	\$ 7,347	\$ 123,304
Impairment	—	(3,610)	—	(3,610)
Balance at December 31, 2022	<u>\$ 112,347</u>	<u>\$ —</u>	<u>\$ 7,347</u>	<u>\$ 119,694</u>

## Intangible Assets, Net

Intangible assets, net consisted of the following:

	December 31, 2022	December 31, 2021	Estimated Useful Lives
Amortizable intangible assets:			
Developed technology	\$ 16,810	\$ 16,810	11 – 16 years
Customer relationships	2,413	2,413	10 years
Trade names & trademarks	570	570	10 – 13 years
Reacquired rights	4,200	4,200	6 years
	<u>23,993</u>	<u>23,993</u>	
Less: accumulated amortization			
Developed technology	(6,549)	(5,376)	
Customer relationships	(1,435)	(1,170)	
Trade names & trademarks	(275)	(220)	
Reacquired rights	(3,240)	(2,540)	
	<u>(11,499)</u>	<u>(9,306)</u>	
Amortizable intangible assets, net	12,494	14,687	
Non-amortized intangible assets			
Acquired IPR&D product rights	108,500	108,500	indefinite
	<u>\$ 120,994</u>	<u>\$ 123,187</u>	

Amortization expense for intangible assets was \$2,193 and \$2,192 for the years ended December 31, 2022 and 2021, respectively.

Aggregate amortization expense for each of the five succeeding years related to intangible assets held as of December 31, 2022 is estimated as follows:

2023	\$ 2,193
2024	\$ 1,753
2025	\$ 1,493
2026	\$ 1,356
2027	\$ 1,258

## 9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2022	2021
Accrued clinical trial expense	\$ 2,659	\$ 1,861
Accrued professional fees	880	1,653
Accrued R&D software	7,333	—
Accrued wages, bonuses, commissions and vacation	2,576	3,824
Accruals for construction in progress	322	—
Deferred rent	—	2
Other	2,632	4,321
	<u>\$ 16,402</u>	<u>\$ 11,661</u>

## 10. Debt

### Yorkville

On September 15, 2022, the Company entered into a Pre-Paid Advance Agreement (the “PPA”) with YA II PN, Ltd. (“Yorkville”), pursuant to which the Company may request advances of up to \$40,000 in cash from Yorkville (or such greater amount that the parties may mutually agree) (each, a “Pre-Paid Advance”) over an 18-month period, with an aggregate limitation of \$150,000. Pre-Paid Advances are issued at a 2% discount, bear interest at an annual rate equal to 6% (increased to 15% in the event of default as described in the PPA) and may be offset by the issuance of shares of common stock, at Yorkville’s option, at a price per share calculated pursuant



to the PPA, which in no event will be less than \$0.75 per share. The issuance of the shares under the PPA is subject to certain limitations, including that the aggregate number of shares of common stock issued pursuant to the PPA cannot exceed 19.9% of the Company's outstanding stock as of September 15, 2022, as well as a beneficial ownership limitation of 4.99%. Further, Yorkville agreed not to purchase any shares of common stock for 60 days following entry into the PPA, nor may Yorkville purchase more than \$6,000 of shares of common stock during a 30-day period, in each case at a price per share less than the Fixed Price, as defined in the PPA. In the event the daily volume weighted average price ("VWAP") of the Class A common stock is below \$0.75 for any five of seven consecutive trading days, the Company will pay Yorkville a monthly cash payment of \$6,000, plus any accrued and unpaid interest along with a 5.0% redemption premium until such time as the daily VWAP for five consecutive trading days immediately prior to the due date of the next monthly payment is at least 10% greater than \$0.75. On February 22, 2023, Yorkville provided notice to the Company that a "triggering event" under the term of the PPA occurred on February 21, 2023. Refer to Note 21 for additional information regarding subsequent events.

In connection with the entry into the PPA, the Company received the initial Pre-Paid Advance of \$40,000 gross or \$39,200 net of discount. Each Pre-Paid Advance has a maturity of 12 months. Further Pre-Paid Advances will be based upon the mutual agreement of the parties. At issuance, the Company concluded that certain features of the PPA would be considered a derivative that would require bifurcation. In lieu of bifurcation, the Company elected the fair value option for this financial instrument and will record changes in fair value within the statements of operations and comprehensive income (loss) at the end of each reporting period. Under the fair value option, upon derecognition the Company will include in net income the cumulative amount of the gain or loss on the debt that resulted from changes in instrument-specific credit risk. Direct costs and fees related to the PPA were recognized in earnings. During the fourth quarter of 2022, Yorkville elected to convert \$3,000 of principal and \$694 of accrued interest into 2,627,968 shares of common stock and \$11 was recognized in earnings from changes in instrument-specific credit risk. As of December 31, 2022, the fair value of the debt was \$37,603 and the principal balance was \$37,000. Refer to Note 4 for additional details regarding the fair value measurement.

### ***Short-Term Borrowings – Related Party***

On June 8, 2021, Legacy Celularity entered into a \$5,000 loan agreement with C.V. Starr & Co., Inc. ("C.V. Starr"), a stockholder of the Company. The loan accrued interest on outstanding principal at a rate equal to (a) 8.0% per year until, and including, July 31, 2021 and (b) 10.0% per year commencing on and including August 1, 2021. Accrued and unpaid interest was payable on July 31, 2021, the last day of each month thereafter, on the date of any prepayment of the loan, on the maturity date and, after the maturity date, on demand. The loan was required to be paid in full on the earlier of (i) June 8, 2022, (ii) the date of the consummation of the Business Combination and (iii) the date the outstanding principal was declared due and payable by C.V. Starr as remedy to an event of default (the "Maturity Date"). On the earlier of (i) the Maturity Date or (ii) the date on which the loan was repaid in full and the commitments of C.V. Starr were terminated, Legacy Celularity was required to pay C.V. Starr an exit fee in an amount equal to 2.0% of the aggregate principal amount of the loan advanced.

Under the terms of the loan, Legacy Celularity could not permit the aggregate amount of cash and cash equivalents to be less than \$5,000 for more than five consecutive business days. Legacy Celularity could not borrow an additional \$5,000 under the loan agreement should it project that the aggregate amount of its cash and cash equivalents would be less than \$5,000 prior to the consummation of the Business Combination.

During the year ended December 31, 2021, the Company repaid amounts outstanding under the short-term borrowing arrangement with C.V. Starr and the arrangement was cancelled. Total amount paid to C.V. Starr was \$5,146, which included principal, accrued interest and the exit fee.

## **11. Leases**

### ***Lease Agreements***

As discussed in Note 2, on January 1, 2022, the Company adopted ASU 2016-02 issued by the FASB related to leases that outlines a comprehensive lease accounting model and supersedes the prior lease guidance. The Company adopted this guidance using the modified retrospective approach and elected the optional transition method. As a result, comparative prior periods in the Company's consolidated financial statements are not adjusted for the impacts of the new standard.

Adoption of ASU 2016-02 resulted in the recording of additional net lease assets and lease liabilities of approximately \$13,001 and \$27,723, respectively, as of January 1, 2022. Incremental borrowing rates as of January 1, 2022, the date the new standard was adopted, were used to calculate the present value of the Company's lease portfolio as of that date. Leases previously identified as build-to-suit leases were derecognized pursuant to the transition guidance provided for build-to-suit leases in ASU 2016-02. The impact of the derecognition of the build-to-suit lease was a net reduction of \$3,993 to accumulated deficit calculated as of January 1, 2022. The standard did not materially impact the consolidated net income (losses) or operating cash flows.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The Company's lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date to determine the appropriate discount rate by multiple asset classes. Variable lease payments that are not based on an index or that result from changes to an index subsequent to the initial measurement of the corresponding lease liability are not included in the measurement of lease ROU assets or liabilities and instead are recognized in earnings in the period in which the obligation for those payments is incurred. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise any such options. Lease expense is recognized on a straight-line basis over the expected lease term. Lease expense was \$3,803 and \$1,132 for the years ended December 31, 2022 and 2021, respectively.

In September 2017, Legacy Celularity entered into an operating lease for office space in Warren, New Jersey, which was set to expire in 2022. In connection with entering into this lease agreement, Legacy Celularity issued a letter of credit of \$481, which is classified as restricted cash (non-current) on the consolidated balance sheets as of December 31, 2020. During the second quarter of 2021, the full \$481 was drawn by the landlord. During the third quarter of 2021, the lease for office space in Warren, New Jersey was terminated.

On September 10, 2019, Legacy Celularity extended the operating lease for the office and laboratory space in Cedar Knolls, New Jersey on a month-to-month basis. Beginning November 1, 2019, Legacy Celularity began paying the landlord the base annual rent and all additional rent at a 2% increase, pro-rated monthly for each month it remains in possession of the premises. Monthly lease payments of \$15 due under the lease included base rent and ancillary charges. Effective October 31, 2022, the Company terminated the Cedar Knolls monthly lease.

On March 13, 2019, Legacy Celularity entered into a lease agreement for a 147,215 square foot facility consisting of office, manufacturing and laboratory space in Florham Park, New Jersey, which expires in 2036. The Company has the option to renew the term of the lease for two additional five-year terms so long as the lease is then in full force and effect. The lease term commenced on March 1, 2020 subject to an abatement of the fixed rent for the first 13 months following the lease commencement date. The initial monthly base rent is approximately \$230 and will increase annually. The Company is obligated to pay real estate taxes and costs related to the premises, including costs of operations, maintenance, repair, replacement and management of the new leased premises. In connection with entering into this lease agreement, Legacy Celularity issued a letter of credit of \$14,722 which is classified as restricted cash (non-current) on the consolidated balance sheets as of December 31, 2022 and 2021. The lease agreement allows for a landlord provided tenant improvement allowance of \$14,722 to be applied to the costs of the construction of the leasehold improvements.

The Company is not the legal owner of the leased space. However, in accordance with prior lease guidance under ASC 840, *Leases*, the Company was deemed to be the owner of the leased space, including the building shell, during the construction period because of the Company's expected level of direct financial and operational involvement in the substantial tenant improvement. As discussed in Note 2, leases previously identified as build-to-suit leases were derecognized pursuant to the transition guidance provided for build-to-suit leases in ASU 2016-02.

The impact of the adoption of ASC 842 is as follows:

	Balance as of December 31, 2021	Adjustments due to adoption of ASC 842	Balance as of January 1, 2022
<b>Assets</b>			
Property and equipment, net	\$ 90,625	\$ (12,421)	\$ 78,204
Operating lease right-of-use-assets	-	13,001	13,001
<b>Liabilities</b>			
Current lease liabilities - operating	-	-	-
Current portion of financing obligation	3,051	(3,051)	-
Noncurrent lease liabilities - operating	-	27,723	27,723
Financing obligations	28,085	(28,085)	-
<b>Stockholders' equity</b>			
Accumulated deficit	\$ (663,681)	\$ 3,993	\$ (659,688)

The components of the Company's lease costs are classified on its consolidated statements of operations as follows:

	Year Ended December 31, 2022
Operating lease cost	\$ 3,038
Variable lease cost	1,598
Total operating lease cost	\$ 4,636
Short term lease cost	\$ 126

The table below shows the cash and non-cash activity related to the Company's lease liabilities during the year ended December 31, 2022:

	Year Ended December 31, 2022
<b>Cash paid related to lease liabilities:</b>	
Operating cash flows from operating leases	\$ 2,834

**Non-cash lease liability activity:**

Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	\$ -

As of December 31, 2022, the maturities of the Company's operating lease liabilities were as follows:

2023	\$ 2,895
2024	2,969
2025	3,042
2026	3,116
2027	3,190
Thereafter	70,341
Total lease payments	85,553
Less imputed interest	(57,568)
Total	\$ 27,985

As of December 31, 2022, the weighted average remaining lease term of the Company's operating lease was 23.3 years, and the weighted average discount rate used to determine the lease liability for the operating lease was 11.12%.

## 12. Commitments and Contingencies

### *Contingent Consideration Related to Business Combinations*

In connection with the Company's acquisition of HLI Cellular Therapeutics, LLC and Anthrogenesis, the Company has agreed to pay future consideration to the sellers upon the achievement of certain regulatory and commercial milestones. As a result, the Company recorded \$105,945 and \$232,222 as contingent consideration as of December 31, 2022 and 2021, respectively. Due to the contingent nature of these milestone and royalty payments, there is a high degree of management estimates that determine the fair value of the contingent consideration. See Note 4 for further discussion.

### *Indemnification Agreements*

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2022 and 2021.

### ***Agreement with Palantir Technologies Inc.***

On May 5, 2021, Legacy Celularity executed a Master Subscription Agreement with Palantir under which it will pay \$40,000 over five years for access to Palantir's Foundry platform along with certain professional services. The Company intended to utilize Palantir's Foundry platform to secure deeper insights into data obtained from the Company's discovery and process development, as well as manufacturing and biorepository operations. In January 2023, the Company ceased use of the software and provided a notice of dispute to Palantir on the basis that the software has not performed as promised and that Palantir has failed to provide the Company with the professional services necessary to successfully implement, integrate and enable the Foundry platform. For the years ended December 31, 2022 and 2021, the Company has recorded costs of \$8,000 and \$5,333, respectively, on a straight-line basis related to this agreement, which was included as a component of research and development expense in the consolidated statements of operations.

### ***Sirion License Agreement***

In December 2021, the Company entered into a license agreement ("Sirion License") with Sirion Biotech GmbH ("Sirion"). Under the Sirion License, Sirion granted the Company a license related to patent rights and know-how associated with poloxamers ("Licensed Product"). As part of the Sirion License, the Company paid Sirion \$136 as an upfront fee, a \$113 annual maintenance fee and may owe up to \$5,099 million related to clinical and regulatory milestones for each Licensed Product during the term. The Company also agreed to pay Sirion low-single digit royalties on net sales on a Licensed Product-by-Licensed Product and country-by-country basis and until the later of: (i) expiration of the last to expire valid claim of the patents covering such Licensed Product, and (ii) 10 years after first Commercial Sale of a Licensed Product. In addition, the Sirion License is subject to termination rights including for termination for material breach and by the Company for convenience upon 30 days written notice. During the year ended December 31, 2022, no milestones have been achieved.

### ***Legal Proceedings***

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

On March 24, 2021, CTH Biosourcing LLC ("CTH") filed a petition and request for disclosure in the District Court of Travis County, Texas seeking declaratory relief challenging Legacy Celularity's for-cause termination of a Tissue Procurement Agreement ("TPA"). During the year ended December 31, 2021, the Company entered into a tri-party settlement (the "Settlement Agreement") with CTH and the CariCord participating shareholders, as interested parties, in which the Company agreed to amend the TPA in exchange for a full release of all claims underlying the aforementioned litigation. In addition, the Company issued 743,771 shares of Class A Common Stock to the CariCord participating shareholders, with an estimated fair value of \$5,333 in exchange for a full release. This amount was recorded as a legal settlement expense within selling, general and administrative in the statements of operations for the year ended December 31, 2021.

Pursuant to the Settlement Agreement, the CariCord participating shareholders are entitled to receive up to an additional 371,885 shares of Class A Common Stock if certain procurement targets are met by CTH under the TPA during a specified period of two years from the effective date of the Settlement Agreement. As of December 31, 2022, the Company considered it probable that certain procurement targets would be met under the Settlement Agreement, resulting in a liability with an estimated fair value of \$186 (see Note 4). As of December 31, 2021, these procurement targets were not probable of being achieved. Due to changes in the Company's common share price and the contingent nature of these procurement targets, the Company cannot predict the amount of such potential issuances.

The Company received a Civil Investigative Demand (the "Demand") under the False Claims Act, 31 U.S.C. § 3729, dated August 14, 2022, from the U.S. Attorney's Office for the Eastern District of Pennsylvania. The Demand requests documents and information relating to claims submitted to Medicare, Medicaid, or other federal insurers for services or procedures involving injectable human tissue therapy products derived from amniotic fluid or birth tissue and includes Interfyl. The Company is cooperating with the request and is engaged in an ongoing dialogue with the Assistant U.S. Attorneys handling the Demand. The matter is still in preliminary stages and there is uncertainty as to whether the Demand will result in any liability.

## **13. Equity**

### ***Common Stock***

#### **Subsequent to Business Combination**

As of December 31, 2022 and 2021, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 730,000,000 shares of \$0.0001 par value Class A common stock.

### *Voting Power*

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of common stock possess all voting power for the election of the Company's directors and all other matters requiring stockholder action. Holders of common stock are entitled to one vote per share on matters to be voted on by stockholders.

### *Dividends*

Holders of Class A Common Stock will be entitled to receive such dividends, if any, as may be declared from time to time by the Company's board of directors in its discretion out of funds legally available therefor. In no event will any stock dividends or stock splits or combinations of stock be declared or made on common stock unless the shares of common stock at the time outstanding are treated equally and identically.

### *Liquidation, Dissolution and Winding Up*

In the event of the Company's voluntary or involuntary liquidation, dissolution, distribution of assets or winding-up, the holders of the common stock will be entitled to receive an equal amount per share of all of the Company's assets of whatever kind available for distribution to stockholders, after the rights of the holders of the preferred stock have been satisfied.

### *Preemptive or Other Rights*

The Company's stockholders have no preemptive or other subscription rights and there are no sinking fund or redemption provisions applicable to common stock.

### *Election of Directors*

The Company's board of directors is divided into three classes, Class I, Class II and Class III, with only one class of directors being elected in each year and each class serving a three-year term, except with respect to the election of directors at the special meeting held in connection with the merger with GX. Class I directors are elected to an initial one-year term (and three-year terms subsequently), the Class II directors are elected to an initial two-year term (and three-year terms subsequently) and the Class III directors are elected to an initial three-year term (and three-year terms subsequently). There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors.

### Prior to Business Combination

As of December 31, 2020, Legacy Celularity's certificate of incorporation, as amended and restated, authorized Legacy Celularity to issue 155,640,290 shares of \$0.0001 par value common stock. The voting, dividend and liquidation rights of the holders of Legacy Celularity's common stock were subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock (as set forth below).

Each share of common stock entitled the holder to one vote on all matters submitted to a vote of Legacy Celularity stockholders. The holders of common stock, voting exclusively and as a separate class, were entitled to elect one director of the Legacy Celularity. Common stockholders were entitled to receive dividends, as was declared by the board of directors, if any, subject to the preferential dividend rights of Preferred Stock. Through the Closing Date, no cash dividends were declared or paid.

As of December 31, 2020, Legacy Celularity had 90,834 of repurchased shares recorded as treasury stock. On the Closing Date, previously existing Legacy Celularity shares held in treasury were cancelled without any conversion.

### ***Preferred Stock***

#### Subsequent to Business Combination

The Company's Certificate of Incorporation authorized 10,000,000 shares of preferred stock and provides that shares of preferred stock may be issued from time to time in one or more series. The Company's board of directors is authorized to fix the voting rights, if any, designations, powers and preferences, the relative, participating, optional or other special rights, and any qualifications, limitations and restrictions thereof, applicable to the shares of each series of preferred stock. The Company's board of directors is able to, without stockholder approval, issue preferred stock with voting and other rights that could adversely affect the voting power and other rights of the holders of common stock and could have anti-takeover effects. The ability of the Company's board of directors to issue preferred stock without stockholder approval could have the effect of delaying, deferring or preventing a change of control of Celularity or the removal of existing management. As of December 31, 2022 and 2021, the Company does not have any outstanding preferred stock.



## Prior to Business Combination

Legacy Celularity issued Series A convertible redeemable preferred stock (the “Series A Preferred Stock”), Series B convertible redeemable preferred stock (the “Series B Preferred Stock”), and Series X convertible redeemable preferred stock (the “Series X Preferred Stock”). The Series A Preferred Stock, Series B Preferred Stock, and Series X Preferred Stock are collectively referred to as the “Preferred Stock”. Immediately prior to closing of the Business Combination on July 16, 2021, the outstanding shares of Preferred Stock were converted into shares of Legacy Celularity common stock and then exchanged for the Company’s Class A common stock at the Effective Time. As of December 31, 2020, Legacy Celularity certificate of incorporation, as amended and restated, authorized Legacy Celularity to issue a total of 116,526,341 shares of Preferred Stock, with a par value of \$0.0001 per share. As of December 31, 2020, no shares of Preferred Stock remained undesignated.

The holders of Preferred Stock had liquidation rights in the event of a deemed liquidation that, in certain situations, were not solely within the control of Legacy Celularity. Therefore, the Preferred Stock was classified outside of stockholders’ deficit on the consolidated balance sheets.

On March 16, 2020, Legacy Celularity entered into a Series B Preferred Stock Purchase Agreement (the “Purchase Agreement”) with certain institutional investors and certain individual investors (collectively “Investors”). Pursuant to the terms of the Purchase Agreement, Legacy Celularity sold and issued to the Investors an aggregate of 13,620,063 shares of Series B Preferred Stock and warrants to purchase up to an aggregate of 13,281,386 shares of Series B Preferred Stock for an aggregate purchase price of approximately \$102,550. Legacy Celularity utilized a probability-weighted option pricing model to determine the fair value of the warrants at the issuance date with the residual proceeds allocated to the Series B Preferred Stock. Based on this valuation, Legacy Celularity determined the purchase price allocated to the Series B Preferred Stock was \$84,596 and the purchase price allocated to the warrants was \$17,954.

Legacy Celularity’s classified Preferred Stock in accordance with ASC 480, *Distinguishing Liabilities from Equity*, which required that contingently redeemable securities be classified outside of permanent stockholders’ equity. Accordingly, Legacy Celularity classified all shares and classes of Preferred Stock as mezzanine equity on the accompanying consolidated balance sheet at December 31, 2021.

## ***Rights, Preferences and Privileges of the Preferred Stock***

The holders of the Preferred Stock had the following rights and preferences except where noted:

### *Voting*

The holders of Preferred Stock were entitled to vote, together with the holders of common stock as a single class, on all matters submitted to stockholders for a vote and had the right to vote the number of shares equal to the number of shares of common stock into which each share of Preferred Stock could convert on the record date for determination of stockholders entitled to vote.

As long as there were at least 5,000,000 shares of Series B Preferred Stock outstanding, the holders of Series B Preferred Stock, voting as a separate class, could elect one director of Legacy Celularity. The remaining directors were elected by holders of common stock and Preferred Stock, voting together as a single class on an as converted basis.

### *Conversion*

Each share of Preferred Stock was convertible, at the option of the holder, at any time after the date of issuance. In addition, each share of Preferred Stock could automatically converted into shares of common stock at the applicable conversion ratio then in effect (i) upon the closing of a firm-commitment public offering resulting in at least \$50,000 of gross proceeds to Legacy Celularity at a price of at least \$9.41 per share of common stock, subject to appropriate adjustment of any recapitalization (“Qualified IPO”), or (ii) upon the written consent of the holders of a majority of the then-outstanding shares of Preferred Stock, voting together as a single class.

The conversion ratio of each series of Preferred Stock was determined by dividing the Original Issue Price of each series by the Conversion Price of each series. The Original Issue Price per share was \$6.27 for Series A and X Preferred Stock (the “Series A and X Original Issue Price”) and \$7.53 for Series B Preferred Stock (the “Series B Original Issue Price”), each subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization and other adjustments as set forth in Legacy Celularity’s certificate of incorporation, as amended and restated. As of December 31, 2020 and the Closing Date, the Conversion Price was equal to the Original Issue Price for each series of Preferred Stock. Accordingly, as of December 31, 2020 and the Closing Date, each share of each series of Preferred Stock was convertible into shares of Legacy Celularity common stock on a one-for-one basis.

## *Dividends*

The holders of Preferred Stock were entitled to receive noncumulative dividends when, as and if declared by the board of directors. Dividends accrued on the Preferred Stock at a rate of 6% of the Original Issue Price per year; however, such dividends were only payable when, as and if declared by the board of directors. Holders of the Preferred Stock were to be paid dividends prior and in preference to any dividends on common stock. As of the Closing Date, no cash dividends were declared or paid.

## *Liquidation*

In the event of any voluntary or involuntary liquidation, dissolution or winding up of Legacy Celularity or Deemed Liquidation Event (as defined below), each holder of the then-outstanding Preferred Stock was entitled to receive the greater of (i) an amount equal to the Original Issue Price for each series of Preferred Stock plus any dividends declared but unpaid thereon or (ii) the amount such holder would have received if such holder had converted its shares into common stock immediately prior to such liquidation event at the conversion price. In the event that the assets available for distribution to stockholders were insufficient to pay Preferred Stockholders the full amounts to which they were entitled, the assets available for distribution were to be distributed on a pro rata basis among the holders of the Preferred Stock in proportion to the respective amounts that would otherwise be payable in respect of such shares.

After the payment of all preferential amounts to the holders of Preferred Stock, then, to the extent available, the remaining assets of Legacy Celularity were to be distributed among the holders of common stock, pro rata based on the number of shares held by each such holder.

Unless (i) the holders of Series B Preferred Stock received an amount less the Original Issue Price or (ii) the holders of majority of the then-outstanding Preferred Stock, voting together as a single class, elect otherwise, a Deemed Liquidation Event included a merger or consolidation (other than one in which stockholders of Legacy Celularity own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of Legacy Celularity.

## *Redemption*

Legacy Celularity's certificate of incorporation, as amended and restated, did not provide redemption rights to the holders of Preferred Stock.

## *ATM Agreement*

On September 8, 2022, the Company entered into an At-the-Market Sales Agreement (the "ATM Agreement") with BTIG, LLC, Oppenheimer & Co. Inc. and B. Riley Securities, Inc., acting as sales agents and/or principals, pursuant to which the Company may offer and sell, from time to time in its sole discretion, shares of its common stock, having an aggregate offering price of up to \$150,000, subject to certain limitations as set forth in the ATM Agreement. The Company is not obligated to make any sales of shares under the ATM Agreement.

Any shares offered and sold in the at-the-market offering will be issued pursuant to the Company's effective shelf registration statement on Form S-3 and the related prospectus supplement. Under the ATM Agreement, the sales agents may sell shares of common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended. The Company will pay the sales agents a commission rate of up to 3% of the gross sales proceeds of any shares sold and has agreed to provide the sales agents with customary indemnification, contribution and reimbursement rights. The ATM Agreement contains customary representations and warranties and conditions to the placements of the shares pursuant thereto.

During the year ended December 31, 2022, the Company received gross and net proceeds of \$6,519 and \$6,021 respectively, from the sale of 2,656,413 shares of its common stock at an average price of \$2.45 per share under the ATM Agreement.

## *Warrants*

### Legacy Celularity Warrants

On May 7, 2018, Legacy Celularity granted Dragasac a warrant for the purchase of an aggregate of 16,601,736 shares of Series B Preferred Stock (the "Dragasac Warrant") at an exercise price of \$7.53 per share. On February 15, 2019, Dragasac exercised its rights under the Dragasac Warrant to purchase 6,640,695 shares of Series B Preferred Stock, at an exercise price of \$7.53 per share, for gross proceeds of approximately \$50,000. On May 29, 2019, Legacy Celularity amended and restated the Dragasac Warrant to provide for a reduced exercise price of \$7.29 for the remaining warrant shares in exchange for Dragasac agreeing to purchase 3,431,223 shares of Series B Preferred Stock on or before May 31, 2019. On May 31, 2019, Dragasac exercised its rights under the Dragasac Warrant to purchase 3,431,223 shares of Series B Preferred Stock at a price per share of \$7.29, for gross proceeds of approximately \$25,000. On November 1, 2019, Legacy Celularity again amended the Dragasac Warrant to provide for a reduced exercise price of \$6.77 for the

remaining warrant shares in exchange for Dragasac agreeing to purchase 6,529,818 shares of Series B Preferred Stock on or before November 4, 2019. On November 4, 2019, Dragasac exercised its right to purchase 6,529,818 shares of Series B Preferred Stock, at a price per share of \$6.77, for gross proceeds of approximately \$44,178.

On January 9, 2020, Legacy Celularity issued a warrant for the purchase of an aggregate of 6,529,818 shares of Series B Preferred Stock to Dragasac. The exercise price per share at which the warrant will be exercised shall be the lesser of \$6.77 per share or 80% of either (i) the value attributed to one share of Series B Preferred Stock upon a consummation of a change of control or the closing of a strategic transaction or (ii) the price at which one share of the common stock is sold to the public in an initial public offering. As amended on March 16, 2020, the warrants are exercisable on the first to occur of (a) March 16, 2025, (b) the consummation of Legacy Celularity's initial public offering, (c) the consummation of a change of control and (d) the closing of a strategic transaction pursuant to which Legacy Celularity's stockholders exchange their existing shares of capital stock in Legacy Celularity for shares in a company whose shares are listed on a national stock exchange. The estimated fair value of the warrant of \$11,988 at the issuance date was immediately charged to expense and recorded in expense related to warrant liabilities in the accompanying consolidated statements of operations. The incremental change in fair value resulting from the amendment was also immediately charged to expense and recorded in the same line item.

On January 8, 2021, Legacy Celularity entered into a warrant amendment agreement ("Amendment No. 2") to amend the warrant issued to Dragasac on January 9, 2020, as amended on March 16, 2020. Amendment No. 2 added a cashless exercise provision and eliminated the provision that would have provided for expiration of the warrant upon consummation of the Business Combination. Any portion of the warrant that was unexercised prior to consummation of the Business Combination converted into warrants to purchase shares of the Company's Class A common stock, with the exercise price and number of shares adjusted as per the exchange ratio and the terms of the Merger Agreement (see Note 3). This amendment did not result in any changes to the accounting for these warrants.

On March 16, 2020, Legacy Celularity entered into the Purchase Agreement with the Investors. Pursuant to the terms of the Purchase Agreement, Legacy Celularity sold and issued to the Investors an aggregate of 13,620,063 shares of Series B Preferred Stock and warrants to purchase up to an aggregate of 13,281,386 shares of Series B Preferred Stock for an aggregate purchase price of approximately \$102,550. The warrants are exercisable at a price of \$7.53 per share on the first to occur of (a) the 60-month anniversary of the date of issuance of the warrants, (b) the consummation of Legacy Celularity's initial public offering and (c) the consummation of a change of control. On January 8, 2021, Legacy Celularity entered into a warrant amendment agreement to amend the warrant issued the Investors on March 16, 2020. The warrant was amended to add cashless exercise provisions following the consummation of the Business Combination. Any portion of warrant held by the Investors that was unexercised prior to the consummation of the Business Combination converted into a warrant to purchase shares of the Company's Class A common stock, with the exercise price and number of shares adjusted as per the exchange ratio and the terms of the Merger Agreement (see Note 3). This amendment did not result in any changes to the accounting for these warrants.

On March 1, 2022, Celularity and certain of the related party investors amended and restated the investors' respective Legacy Celularity Warrants to (i) reduce the exercise price per share from \$7.53 per share to \$3.50 per share, subject to adjustment as set forth in the A&R Warrants, (ii) remove the transfer restrictions set forth in the A&R Warrants, and (iii) make other changes reflecting the impact of the business combination. In conjunction with the amendment, those investors exercised 13,281,386 of the A&R Warrants in exchange for 13,281,386 shares of Class A Common Stock for gross proceeds of \$46,485. The Company accounted for the amendment as a cost to issue equity with the incremental fair value of \$15,985 related to the amendment recognized as an offset to the proceeds received. However, because these were equity classified warrants, the net impact to the consolidated statements of convertible preferred stock and stockholders' equity (deficit) was zero.

Prior to the Business Combination, Legacy Celularity classified the warrants as liabilities on its consolidated balance sheets because the warrants were freestanding financial instruments that might have required Legacy Celularity to transfer assets upon exercise. The liability associated with each of these warrants was initially recorded at fair value upon the issuance date of each warrant and was subsequently remeasured to fair value at each reporting date with the final remeasurement occurring on the Closing Date. Changes in the fair value of the warrant liability were recognized as a component of other income (expense), net in the consolidated statements of operations. On the Closing Date, the warrants held by Dragasac and the Investors were converted into warrants to purchase shares of the Company's Class A Common Stock. The aforementioned warrants qualified for equity classification on the Closing Date and were reclassified accordingly.

#### Legacy GX Warrants

Upon consummation of the Business Combination, the Public Warrants and Sponsor Warrants remain outstanding. The Public Warrants became exercisable on August 15, 2021, which is the later of (a) 30 days after the consummation of a Business Combination or (b) 12 months from the effective date of the registration statement relating to GX's initial public offering. No Public Warrants would have been exercisable for cash unless the Company has an effective and current registration statement covering the shares of Class A common stock issuable upon exercise of the Public Warrants and a current prospectus relating to such common shares. Notwithstanding the foregoing, if a registration statement covering the common shares issuable upon the exercise of the Public Warrants were not effective

within 90 days from the consummation of the Business Combination, the holders could have, until such time as there was an effective registration statement and during any period when the Company shall have failed to maintain an effective registration statement, exercise the Public Warrants on a cashless basis pursuant to an available exemption from registration under the Securities Act. If an exemption from registration were not available, holders would not have been able to exercise their Public Warrants on a cashless basis. The Company filed its registration statement on August 12, 2021. The Public Warrants will expire five years from the consummation of the Business Combination or earlier upon redemption or liquidation.

The Company may call the Public Warrants for redemption (excluding the Sponsor Warrants), in whole and not in part, at a price of \$0.01 per warrant:

- at any time while the Public Warrants are exercisable,
- upon not less than 30 days' prior written notice of redemption to each Public Warrant holder, and
- if, and only if, there is a current registration statement in effect with respect to the issuance of the common stock underlying such warrants at the time of redemption and for the entire 30-day trading period referred to above and continuing.

The Sponsor Warrants are identical to the Public Warrants underlying the units sold in GX's initial public offering, except that the Sponsor Warrants and the common shares issuable upon the exercise of the Sponsor Warrants were not transferable, assignable or salable until after the completion of the Business Combination, subject to certain limited exceptions. Additionally, the Sponsor Warrants are exercisable on a cashless basis and are non-redeemable so long as they are held by the initial purchasers or their permitted transferees. If the Sponsor Warrants are held by someone other than the initial purchasers or their permitted transferees, the Sponsor Warrants will be redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

The exercise price and number of shares of Class A common stock issuable upon exercise of the Public Warrants and Sponsor Warrants may be adjusted in certain circumstances including in the event of a share dividend, or recapitalization, reorganization, merger or consolidation.

Additionally, in no event will the Company be required to net cash settle the Public Warrants. If the Company calls the Public Warrants for redemption, management will have the option to require all holders that wish to exercise the Public Warrants to do so on a "cashless basis," as described in the warrant agreement. The exercise price and number of Class A common shares issuable upon exercise of the Public Warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary dividend or recapitalization, reorganization, merger or consolidation.

In order to finance transaction costs in connection with the Business Combination, members of GX's sponsor, GX Sponsor LLC (the "Sponsor"), entered into promissory notes with GX to provide working capital funds. In connection with the Business Combination, 1,499,999 Sponsor Warrants were issued to members of the Sponsor as repayment for the working capital loans made to GX.

#### May 2022 PIPE

On May 18, 2022, the Company entered into a securities purchase agreement with an institutional accredited investor providing for the private placement of (i) 4,054,055 shares of Class A Common Stock and (ii) accompanying warrants to purchase up to 4,054,055 shares of Class A Common Stock (the "May 2022 PIPE Warrants"), for \$7.40 per share and accompanying warrant, or an aggregate purchase price of approximately \$30,000 gross, or \$27,396 net of related costs of \$2,604 which were recorded as a reduction to additional paid-in-capital. The net proceeds were allocated to the warrant liability as noted below with the remainder of \$7,651 recorded in additional paid-in capital. Each warrant has an exercise price of \$8.25 per share, is immediately exercisable, will expire on May 20, 2027 (five years from the date of issuance) (the "May 2022 PIPE Financing"). The closing of the May 2022 PIPE Financing occurred on May 20, 2022. In the event of certain fundamental transactions involving the Company, the holders of May 2022 PIPE Warrants may require the Company to make a payment based on a Black-Scholes valuation, using specified inputs that are not considered indexed to the Company's stock in accordance with ASC 815. Therefore, the Company accounted for the May 2022 PIPE Warrants as liabilities and were recorded at the closing date fair value for \$19,745 which was based on a Black-Scholes option pricing model. The remainder of the proceeds were allocated to the Class A common stock issued and recorded as a component of equity.

As of December 31, 2022, the Company had 33,458,360 outstanding warrants to purchase Class A common stock. A summary of the warrants is as follows:

	Number of Shares	Exercise Price	Expiration Date
Dragasac Warrant	6,529,818	\$ 6.77 *	March 16, 2025
Public Warrants	14,374,488	\$ 11.50	July 16, 2026
Sponsor Warrants	8,499,999	\$ 11.50	July 16, 2026
May 2022 PIPE Warrants	4,054,055	\$ 8.25	May 20, 2027
	<u>33,458,360</u>		



*\* The exercise price is the lesser of \$6.77 per share or 80% of either (i) the value attributed to one share of Legacy Celularity Series B Preferred Stock upon consummation of a change in control or the closing of a strategic transaction or (ii) the price at which one share of common stock is sold to the public market in an initial public offering.*

## **14. Stock-Based Compensation**

### ***2021 Equity Incentive Plan***

In July 2021, the Company's board of directors adopted and the Company's stockholders approved the 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan provides for the grant of incentive stock options ("ISOs") to employees and for the grant of nonstatutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors and consultants.

The number of shares of Class A Common Stock initially reserved for issuance under the 2021 Plan is 20,915,283. As of December 31, 2022, 15,115,658 shares remain available for future grant under the 2021 Plan. The number of shares reserved for issuance will automatically increase on January 1 of each year, for a period of 10 years, from January 1, 2022 through January 1, 2031, by 4% of the total number of shares of Celularity capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Company's board of directors. Shares subject to stock awards granted under the 2021 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under the 2021 Plan. Additionally, shares issued pursuant to stock awards under the 2021 Plan that are repurchased or forfeited, as well as shares that are reacquired as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under the 2021 Plan.

The 2021 Plan is administered by the Company's board of directors. The Company's board of directors, or a duly authorized committee thereof, may delegate to one or more officers the authority to (i) designate employees other than officers to receive specified stock awards and (ii) determine the number of shares to be subject to such stock awards. Subject to the terms of the 2021 Plan, the plan administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under the 2021 Plan. The plan administrator has the power to modify outstanding awards under the 2021 Plan. Subject to the terms of the 2021 Plan and in connection with a corporate transaction or capitalization adjustment, the plan administrator may not reprice or cancel and regrant any award at a lower exercise price, strike price or purchase price or cancel any award with an exercise price, strike price or purchase price in exchange for cash, property or other awards without first obtaining the approval of the Company's stockholders.

### ***2017 Equity Incentive Plan***

The 2017 Equity Incentive Plan (the "2017 Plan") adopted by Legacy Celularity's board of directors and approved by Legacy Celularity's stockholders provided for Legacy Celularity to grant stock options to employees, directors and consultants of Legacy Celularity. In connection with the closing of the Business Combination and effectiveness of the 2021 Plan, no further grants will be made under the 2017 Plan.

The total number of stock options that could have been issued under the 2017 Plan was 32,342,049. Shares that expired, forfeited, canceled or otherwise terminated without having been fully exercised were available for future grant under the 2017 Plan.

The 2017 Plan is administered by the Company's board of directors or, at the discretion of the Company's board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions were determined at the discretion of Legacy Celularity's board of directors, or its committee if so delegated, except that the exercise price per share of stock options could not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option could not be greater than ten years. Stock options granted to employees, officers, members of the board of directors and consultants typically vested over a three or four year period.

### ***Stock Option Valuation***

#### **Awards with Service Conditions**

The fair value of each option is estimated on the date of grant using a Black-Scholes option pricing model that takes into account inputs such as the exercise price, the estimated fair value of the underlying common stock at grant date, expected term, expected stock price volatility, risk-free interest rate, and dividend yield. The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Certain of these inputs are subjective and generally require judgment to determine.



- The expected term of employee stock options with service-based vesting is determined using the “simplified” method, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company’s lack of sufficient historical data. The expected term of non-employee options is equal to the contractual term or our estimated term based on the underlying agreement.
- The expected stock price volatility is based on historical volatilities of comparable public entities within the Company’s industry.
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the respective expected term or contractual term.
- The expected dividend yield is 0% because the Company has not historically paid, and does not expect, for the foreseeable future, to pay a dividend on its common stock.

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted during the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Risk-free interest rate	2.7%	0.8%
Expected term (in years)	5.9	4.7
Expected volatility	77.1%	80.4%
Expected dividend yield	—%	—%

The weighted average grant-date fair value per share of stock options granted during the years ended December 31, 2022 and 2021 was \$5.43 and \$4.13, respectively.

The following table summarizes option activity with service conditions under the 2021 Plan and the 2017 Plan:

	Options	Weighted Average Exercise Price	Weighted Average Contract Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2020	17,167,165	\$ 1.63	7.3	\$ 100,633
Granted	9,681,736	8.57		
Exercised	(703,512)	0.91		
Forfeited	(2,080,803)	4.04		
Outstanding at December 31, 2021	24,064,586	\$ 4.23	7.4	\$ 56,525
Granted	3,353,573	8.00		
Exercised	(1,710,471)	0.56		
Forfeited	(648,279)	7.60		
Outstanding at December 31, 2022	25,059,409	\$ 4.90	6.1	\$ 7,851
Vested and expected to vest December 31, 2022	25,059,409	\$ 4.90	6.1	\$ 7,851
Exercisable at December 31, 2022	20,277,617	\$ 4.15	5.4	\$ 7,851

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company’s Class A Common Stock for those options that had exercise prices lower than the fair value of the Company’s Class A Common Stock.

The Company recorded stock-based compensation expense relating to awards with service conditions of \$10,702 and \$39,122 during the years ended December 31, 2022 and 2021, respectively. During the years ended December 31, 2022 and 2021, the aggregate intrinsic value was \$7,997 and \$2,959 for the stock options exercised, respectively. During the year ended December 31, 2021, there were 131,256 options exercised with a value of \$441 classified as liabilities at December 31, 2021, until the shares were issued to the holder. As of December 31, 2022, unrecognized compensation cost for options issued with service conditions was \$23,508 and will be recognized over an estimated weighted-average amortization period of 2.57 years.

In March 2021, Legacy Celularity’s board of directors approved the issuance of fully vested options to acquire 269,007 shares at \$3.83 per share to each of its non-employee directors. During the second quarter of 2021, the grant notice was provided to the non-employee directors. Accordingly, the grant date was established in the second quarter of 2021 under ASC 718, *Compensation – Stock Compensation* and the Company recognized the commensurate expense.

During the second quarter of 2021, Legacy Celularity's board of directors approved the issuance of fully vested options to acquire a total of 2,613,217 shares at \$10.21 per share to certain members of senior management. Accordingly, the Company recognized the full expense of \$13,723 during the second quarter of 2021, of which \$6,861 was recorded to research and development expense and \$6,862 was recorded to selling, general and administrative expense on the consolidated statements of operations.

In September 2021, the Company's board of directors approved the issuance of options to acquire a total of 3,766,107 shares of common stock at \$10.23 per share to certain members of senior management as a result of the Business Combination (the "Transaction Awards" or "Performance Awards"). The Transaction Awards vested 50% on the Closing Date, with the remaining 50% vesting over four years. Accordingly, the Company recognized expense of \$7,186 during the third quarter of 2021 for the shares that vested on the grant date, of which \$3,388 was recorded to research and development expense and \$3,798 was recorded to selling, general and administrative expense on the consolidated statements of operations.

In July 2021, the Company amended two non-employee stock option awards such that any unvested awards at the time of the Business Combination would become fully vested. The Company accelerated the recognition of \$567 of expense related to the modification of these awards.

#### Awards with Performance Conditions

In connection with the advisory agreement signed with Robin L. Smith, MD (see Note 20), the Company awarded options to acquire a total of 1,050,000 shares with an exercise price of \$2.99 to Dr. Smith, a member of the Company's board of directors. The initial tranche of 250,000 stock options vested upon execution of the advisory agreement on August 16, 2022. The remaining 800,000 stock options are subject to vesting upon achievement of certain predefined milestones in relation to the expansion of the degenerative disease business. On November 1, 2022, the second tranche of 200,000 stock options vested upon achievement of the first milestone. The fair value of the award was determined based on a Black-Scholes option-pricing model. The Company's grant date fair value assumptions were 79.9% expected volatility, 2.95% risk-free interest rate, 5 year expected term, and 0% expected dividend yield. The Company recorded stock-based compensation of \$881 for the year ended December 31, 2022. As of December 31, 2022, the remaining unrecognized compensation cost was \$1,175, and will be recognized upon probable achievement of the milestones.

During 2021, the Company had certain performance-based stock options, which were earned based on the attainment of specified goals achieved over the performance period. During the year ended December 31, 2021, the Company recognized \$31 expense related to the performance awards in which the performance condition was probable until those awards were amended such that the entire unvested portion of the award vested upon closing of the Business Combination. The Company accelerated the recognition of \$121 of expense related to the modification of this award, and as of December 31, 2021, there was no amount of unrecognized expense related to these performance awards.

#### Awards with Market Conditions

In September 2021, the Company awarded options to acquire a total of 2,469,282 shares with an exercise price of \$6.32 to the Company's former President in connection with the commencement of his employment. The grant was comprised of four equal tranches, and would vest in up to five equal installments in respect of achieving certain share price targets between the third and fourth anniversary of the effective date, subject to his continued employment with the Company. The Company's President resigned effective August 31, 2022, and the President's award was terminated at such time and a consulting agreement was signed thereafter, refer to Note 20 for further details. The Company reversed all previously recognized stock-based compensation expense of \$1,681 related to the President's award during the year ended December 31, 2022.

#### ***Restricted Stock Units***

The Company issues RSUs to employees that generally vest over a two-year period with 50% of awards vesting after 1 year and then the remaining 50% vesting after 2 years. Any unvested shares will generally be forfeited upon termination of services. The fair value of an RSU is equal to the fair market value price of the Company's common stock on the date of grant. RSU expense is amortized straight-line over the vesting period.

The following table summarizes activity related to RSU stock-based payment awards:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	—	\$ —
Granted	488,600	\$ 7.20
Forfeited	(13,900)	\$ 7.20
Outstanding at December 31, 2021	474,700	\$ 7.20
Granted	2,342,891	\$ 7.51
Vested	(232,521)	\$ 7.21
Forfeited	(311,041)	\$ 8.46
Outstanding at December 31, 2022	2,274,029	\$ 7.34

The Company recorded stock-based compensation expense of \$4,787 and \$222 for the years ended December 31, 2022 and 2021, related to RSUs. As of December 31, 2022, the total unrecognized expense related to all RSUs was \$13,367, which the Company expects to recognize over a weighted-average period of 2.74 years.

### ***Stock-Based Compensation Expense***

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations:

	Year Ended December 31,	
	2022	2021
Cost of revenues	\$ 410	\$ 72
Research and development	2,118	11,105
Selling, general and administrative	13,328	28,833
	<u>\$ 15,856</u>	<u>\$ 40,010</u>

## **15. Revenue Recognition**

The following table provides information about disaggregated revenue by product and services:

	Year Ended December 31,	
	2022	2021
Product sales and rentals	\$ 3,749	\$ 3,801
Services	5,512	5,522
License, royalty and other	8,714	12,012
Net revenues	<u>\$ 17,975</u>	<u>\$ 21,335</u>

The following table provides changes in deferred revenue from contract liabilities:

	2022	2021
Balance at January 1	\$ 4,067	\$ 12,449
Deferral of revenue*	5,004	4,928
Recognition of unearned revenue**	(4,579)	(13,310)
Balance at December 31	<u>\$ 4,492</u>	<u>\$ 4,067</u>

\* Deferral of revenue resulted from payments received in advance of performance under the biobanking services storage contracts that are recognized as revenue under the contract as performance is completed.

\*\* During the third quarter of 2021, the Company terminated the license agreement with Sanuwave due to an uncured material breach (See Note 16). As a result, the Company recognized the remaining deferred revenue of \$6,754 that was to be recognized on a straight-line basis over the non-cancelable term of the license agreement.

## **16. License and Distribution Agreements**

### ***Sorrento Therapeutics, Inc. License and Transfer Agreement***

On August 15, 2017, Legacy Celularity entered into a License and Transfer Agreement with TNK Therapeutics, Inc. and Sorrento Therapeutics, Inc. (collectively “Sorrento”), pursuant to which Legacy Celularity was granted an exclusive license to certain materials,

patents and intellectual property related to Sorrento to develop and commercialize products for the treatment of any disease or disorder (the “2017 License Agreement”). During the first quarter of 2020, the 2017 License Agreement was mutually terminated.

On August 26, 2020, Legacy Celularity and Sorrento entered into a binding term sheet for the exclusive worldwide license to CD19 CAR-T constructs for use in placenta-derived cells for the treatment of any disease or disorder (the “2020 Sorrento Term Sheet”). The 2020 Sorrento Term Sheet outlined various provisions to be incorporated and further negotiated in contemplation of a final license and supply agreement.

On September 30, 2020, Legacy Celularity and Sorrento entered into a new License and Transfer Agreement for the exclusive worldwide license to CD19 CAR-T constructs for use in placenta-derived cells and/or cord blood-derived cells for the treatment of any disease or disorder (the “2020 Sorrento License Agreement”). The Company retains the right to sublicense the rights granted under the agreement with Sorrento’s prior written consent. As consideration for the license, the Company is obligated to pay Sorrento a royalty equal to low single-digit percentage of net sales (as defined within the agreement) and a royalty equal to low double-digit percentage of all sublicensing revenues (as defined within the agreement). The 2020 Sorrento License Agreement will remain in effect until terminated by either the Company or Sorrento for uncured material breach upon 90 days written notice or, after the first anniversary of the effective date of the Sorrento Agreement, by the Company for convenience upon six months’ written notice to Sorrento.

The Company and Sorrento are actively negotiating a new supply agreement related to the 2020 Sorrento License Agreement. The 2020 Sorrento Term Sheet details certain aspects of this supply agreement, including pricing terms on material and/or licensed product supplied under the 2020 Sorrento License Agreement. The Company did not incur incentive payments related to the 2020 Sorrento Term Sheet.

#### ***Lung Biotechnology PBC License Agreement***

On June 30, 2017, Legacy Celularity entered into a license agreement with Lung Biotechnology PBC (“LB”), a wholly owned subsidiary of United Therapeutics Corporation (the “LB Agreement”), whereupon Legacy Celularity granted to LB an exclusive, worldwide sublicensable license of certain intellectual property to develop and commercialize products in the fields of thoracic and abdominal organ transplantation and pulmonary diseases (the “LB Licensed IP”). Pursuant to the LB Agreement, Legacy Celularity agreed to supply LB with placental-derived stem cells for use in the development and commercialization of products.

On April 3, 2020, Legacy Celularity and LB agreed to expand their strategic collaborative license agreement to include treatment of COVID-19 and Acute Respiratory Distress Syndrome (“ARDS”). Under the amended collaborative agreement, the Company will seek regulatory approval for CYNK-001 in the treatment of COVID-19, and LB will seek regulatory approval for CYNK-001 in the treatment of ARDS. LB has global rights under the amended collaborative agreement to commercialize CYNK-001 in the treatment of COVID-19 and ARDS. The collaboration will be governed by a joint steering committee to oversee development and commercialization activities. LB will provide financial support as needed and requested by Legacy Celularity, subject to a maximum of \$75 per enrolled patient in the related clinical studies, which will be recorded as an offset to research and development expense.

During the first quarter of 2021, the license agreement with LB was terminated in its entirety effective April 11, 2021. The termination applies to the April 3, 2020 amendment for the treatment of CYNK-001 in COVID-19 and ARDS.

#### ***Genting Innovation PTE LTD Distribution Agreement***

On May 4, 2018, concurrently with Dragasac’s equity investment in Legacy Celularity, Legacy Celularity entered into a distribution agreement with Genting Innovation PTE LTD (“Genting”) pursuant to which Genting was granted supply and distribution rights to certain Company products in select Asia markets (the “Genting Agreement”). The Genting Agreement grants Genting limited distribution rights to the Company’s then-current portfolio of degenerative disease products and provides for the automatic rights to future products developed by or on behalf of the Company.

The term of the Genting Agreement was renewed on January 31, 2023, and automatically renews for successive twelve month terms unless: Genting provides written notice of its intention not to renew at least three months prior to a renewal term or the Genting Agreement is otherwise terminated by either party for cause.

Genting and Dragasac are both direct subsidiaries of Genting Berhad, a public limited liability company incorporated and domiciled in Malaysia.

#### ***Celgene Corporation License Agreement***

In connection with the Anthrogenesis acquisition, on August 20, 2017, Legacy Celularity entered into a license agreement with Celgene (the “Celgene Agreement”) pursuant to which the Company granted Celgene two separate licenses to certain intellectual property owned or controlled by Anthrogenesis as of the date of the Company’s acquisition of Anthrogenesis (the “Anthrogenesis IP”). The Celgene Agreement grants Celgene a royalty-free, fully-paid up, worldwide, non-exclusive license to the Anthrogenesis IP for pre-

clinical research purposes in all fields and a royalty-free, fully-paid up, worldwide license, with the right to grant sublicenses, to the Anthrogenesis IP for the development, manufacture, commercialization and exploitation of products in the field of the construction of any CAR, the modification of any T-lymphocyte or NK cell to express such a CAR, and/or the use of such CARs or T-lymphocytes or NK cells for any purpose, including prophylactic, diagnostic, and/or therapeutic uses thereof. The Celgene Agreement will remain in effect until its termination by either party for cause.

### ***Sanuwave Licensing Agreement***

On August 6, 2020, in conjunction with the sale of the UltraMIST business, Legacy Celularity entered into a five-year licensing arrangement with Sanuwave that includes (i) an exclusive Biovance license for distribution and commercialization in the wound care market worldwide, except for certain Asian jurisdictions and (ii) a non-exclusive license for the distribution and commercialization of Interfyl in the wound care market worldwide, except for certain Asian jurisdictions (the “Sanuwave Licensing Agreement”). Sanuwave had the right to grant sublicenses of the exclusive Biovance license and non-exclusive Interfyl license to (i) its affiliates without the consent of the Company and (ii) any third party for the sole purpose of providing services directly to Sanuwave upon prior written consent by the Company.

During the second quarter of 2021, Legacy Celularity sent a notice of deficiency to Sanuwave under the existing license agreement, where Sanuwave had until July 19, 2021 to cure a material breach. This material breach was not cured by Sanuwave and, as a result, the agreement with Sanuwave was terminated during the third quarter of 2021.

### ***Exclusive Supply and Distribution Agreements***

On May 7, 2021, the Company entered into a six-year supply and distribution agreement with Arthrex, Inc. ("Arthrex") that includes (i) an exclusive Biovance, Interfyl, and Centaflex license for distribution and commercialization within the United States for the orthopedic surgery and (ii) an exclusive Interfyl and Centaflex license for commercialization and distribution within the United States for the acute and chronic non-healing wound market (the “Arthrex Supply and Distribution Agreement”). The Arthrex Supply and Distribution Agreement will automatically renew for terms of two-year periods unless either party gives notice of non-renewal at least twelve months advance of the end of the then current term. At least ninety days prior to the start of each calendar quarter, the Company and Arthrex will agree in good faith to a minimum binding forecast based upon projected sales volume by Arthrex for said upcoming calendar quarter for each of the products. Upon agreement, Arthrex shall submit to the Company a purchase order to purchase products for the minimum forecasted quantities. The Company shall invoice Arthrex after the product has been issued and payments for such invoices will be 2%, ten net forty-five days from the date of the invoice. Upon material breach of the Arthrex Supply and Distribution Agreement either party may deliver such breach to the other party and the notified party will have thirty days to cure such breach. If the notified party fails to cure the material breach of the Arthrex Supply and Distribution Agreement the non-breaching party may terminate the respective agreement. Under the Arthrex Supply and Distribution Agreement, the Company and Arthrex will establish a joint steering committee to oversee commercialization activities of the products. Membership of the joint steering committee will be comprised of an equal number of employees of each respective party.

On September 1, 2021, the Company entered into a three-year supply and distribution agreement with Evolution Biologyx, LLC (“Evolution”) that includes an exclusive Interfyl license for the distribution and commercialization within the United States within any medical specialty where Interfyl is administered in an in-office or in-patient setting and is reimbursed through Medicare Part B or any successor, equivalent or similar category established by the Center for Medicare Services or other Government Authority, except in the medical specialty of orthopedic surgery excluding trauma or spine applications in the medical specialty of orthopedic or neurologic surgery (the “Evolution Supply and Distribution Agreement”). The Evolution Supply and Distribution Agreement will automatically renew for terms of two-year periods unless either party gives notice of non-renewal at least twelve months in advance of the current term. In March 2023, the Company provided notice of material breach to Evolution under the Evolution Supply and Distribution Agreement for Evolution's failure to perform. The Evolution Supply and Distribution Agreement will terminate if the material breach is not cured by Evolution within thirty days of such notice.

## **17. Benefit Plan**

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Matching contributions to the plan may be made at the discretion of the Company’s board of directors. During the years ended December 31, 2022 and 2021, the Company made contributions of \$1,159 and \$989, respectively, to the plan.



## 18. Income Taxes

A summary of the Company's current and deferred tax provision is as follows:

	Year Ended December 31,	
	2022	2021
Current income tax expense:		
Federal	\$ -	\$ -
State	13	17
Total current income tax expense	13	17
Deferred income tax expense (benefit):		
Federal	1	1
State	(1)	2
Total deferred tax expense	—	3
Total expense from income taxes	<u>\$ 13</u>	<u>\$ 20</u>

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefits	(38.9)%	9.8%
Research and development tax credits	0.0%	1.5%
Interest accretion expense	(186.9)%	8.6%
Change in valuation allowance	269.1%	(46.1)%
Mark to market warrant	(58.5)%	2.8%
Deferred true-up	0.2%	1.7%
Stock-based compensation	(8.2)%	0.5%
Impairment	5.3%	—
Other permanent items	(3.1)%	0.2%
Effective income tax rate	<u>(0.0)%</u>	<u>0.0%</u>

Net deferred tax liabilities as of December 31, 2022 and 2021 consisted of the following:

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	\$ 102,723	\$ 88,327
Research and development tax credit carryforwards	5,674	7,672
Stock-based compensation expense	14,321	11,748
Startup costs	588	697
Intangible assets	3,905	4,471
Deferred revenue	1,135	1,103
Unicap	6	6
Imputed interest on contingent payments	5,654	4,410
Legal fee capitalization and amortization	1,342	1,550
Capitalized research and development	19,318	—
Other	3,121	1,535
Total deferred tax assets	157,787	121,519
Deferred tax liabilities:		
In-process research and development	(27,271)	(29,232)
Total deferred tax liabilities	(27,271)	(29,232)
Valuation allowance	(130,525)	(92,297)
Net deferred tax liabilities	<u>\$ (9)</u>	<u>\$ (10)</u>

A reconciliation of the beginning and ending amounts of unrecognized tax benefits is as follows:

	Unrecognized Tax Benefits
Balance at December 31, 2020	\$ 1,028
Increase related to current year tax provisions	242
Balance at December 31, 2021	\$ 1,270
Decrease related to current year tax provisions	(242)
Balance at December 31, 2022	<u>\$ 1,028</u>

As of December 31, 2022 and 2021, the Company had U.S. federal and state net operating loss carryforwards of \$102,723 and \$88,327, respectively, which may be available to offset future taxable income and begin to expire in 2040. As of December 31, 2022 and 2021, the Company also had U.S. federal and state research and development tax credit carryforwards of \$5,674 and \$7,672, respectively, which may be available to offset future tax liabilities and begin to expire in 2032.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to an annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50% over a three-year period. A corporation that experiences an ownership change is subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate subject to additional adjustments, as required. The Company experienced an ownership change on August 15, 2017. The annual limitation from the ownership change is not expected to result in the expiration of net operating losses or research and development credits before utilization.

The realization of deferred tax assets is dependent upon the Company's ability to generate taxable income in future years. ASC 740-10, *Income Taxes*, requires a valuation allowance to be applied against deferred tax assets when it is considered "more likely than not" that some or all of the gross deferred tax assets will not be realized. The Company considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance.

At December 31, 2022, based upon the weight of available evidence, the Company concluded that it is not more likely than not that the benefits of the federal and state deferred tax assets will be realized. Accordingly, the Company has recorded valuation allowance against its federal and state gross deferred tax assets.

The impact of an uncertain income tax position is recognized at the largest amount that is "more likely than not" to be sustained upon audit by the relevant taxing authority. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

As of December 31, 2022 and 2021, the Company had gross unrecognized tax benefits of \$1,028 and \$1,270, respectively. The Company does not expect that there will be a significant change in the unrecognized tax benefits over the next 12 months. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2022 and 2021, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's consolidated statements of operations. The Company files income tax returns in the U.S. and numerous states, as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company is open to future tax examination under statute from 2017 to the present; however, carryforward attributes that were acquired may still be adjusted upon examination by federal, state or local tax authorities if they either have been or will be used in a future period.

During 2021, the Company sold \$1,356 of its net operating losses and unused R&D tax credits through the New Jersey Economic Development Authority's Technology Business Tax Certificate Transfer Program. The income resulting from the sale of net operating losses and unused R&D tax credits is recorded as a component of other income (expense) on the consolidated statements of operations for the year ended December 31, 2021.

## 19. Segment Information

The Company regularly reviews its segments and the approach used by management to evaluate performance and allocate resources. Prior to the third quarter of 2020, Legacy Celularity managed operations as one segment. In the third quarter of 2020, the Company began to manage its operations through an evaluation of three distinct business segments: Cell Therapy, Degenerative Disease, and BioBanking. This change was prompted by certain organizational and personnel changes. The chief operating decision maker uses

the revenues and earnings of the operating segments, among other factors, for performance evaluation and resource allocation among these segments.

The reportable segments were determined based on the distinct nature of the activities performed by each segment. Cell Therapy broadly refers to therapies the Company is researching and developing. Therapies being researched are unproven and in various phases of development. Degenerative Disease produces, sells and licenses products used in surgical and wound care markets. Biobanking collects stem cells from umbilical cords and placentas and provides storage of such cells on behalf of individuals for future use.

The Company manages its assets on a total company basis, not by operating segment. Therefore, the chief operating decision maker does not regularly review any asset information by operating segment and, accordingly, asset information is not reported by operating segment. Total assets were approximately \$401,066 and \$414,128 as of December 31, 2022 and 2021, respectively.

Financial information by segment is as follows:

	Year Ended December 31, 2022				
	Cell Therapy	BioBanking	Degenerative Disease	Other	Total
Net revenues	\$ —	\$ 5,512	\$ 12,463	\$ —	\$ 17,975
Gross profit	—	1,976	(3,666)	—	(1,690)
Direct expenses	75,379	1,699	10,859	56,261	144,198
Segment contribution	<u>(75,379)</u>	<u>277</u>	<u>(14,525)</u>	<u>(56,261)</u>	<u>(145,888)</u>
Indirect expenses				(120,288) (a)	(120,288)
Loss from operations					<u>\$ (25,600)</u>
<i>(a) Components of other</i>					
Change in fair value of contingent consideration liability				(126,277)	
Change in fair value of contingent stock consideration				186	
Goodwill impairment				3,610	
Amortization				2,193	
Total other				<u>\$ (120,288)</u>	

	Year Ended December 31, 2021				
	Cell Therapy	BioBanking	Degenerative Disease	Other	Total
Net revenues	\$ —	\$ 5,522	\$ 15,813	\$ —	\$ 21,335
Gross profit	—	1,873	9,809	—	11,682
Direct expenses	85,107	2,119	8,450	64,018	159,694
Segment contribution	<u>(85,107)</u>	<u>(246)</u>	<u>1,359</u>	<u>(64,018)</u>	<u>(148,012)</u>
Indirect expenses				(38,953) (b)	(38,953)
Loss from operations					<u>\$ (109,059)</u>
<i>(b) Components of other</i>					
Change in fair value of contingent consideration liability				(41,145)	
Amortization				2,192	
Total other				<u>\$ (38,953)</u>	

## 20. Related Party Transactions

The related party transactions described below do not have any associated balances on the consolidated balance sheets as of December 31, 2022 and 2021.

### *Consulting & Advisory Agreements with Dr. Andrew Pecora*

On September 1, 2017, Legacy Celularity entered into a scientific and clinical advisor agreement (the “SAB Agreement”) with Dr. Andrew Pecora, a member of Legacy Celularity’s board of directors, for the provision of consulting and advisory services. The SAB Agreement was superseded by a new SAB Agreement executed by Legacy Celularity on February 1, 2019.

On April 13, 2020, Legacy Celularity executed the First Amendment of the SAB Agreement with Dr. Pecora. The term of the First Amendment was six months. It provided for the payment of \$20 per month and the issuance of a stock option to purchase 153,718 shares of Legacy Celularity’s common stock. This consideration was in addition to consideration defined in prior agreements. Upon the

execution of the agreement, 76,859 of the options were vested. The remaining 76,859 options were vested upon Dr. Pecora's achievement of a performance objective.

On October 15, 2020, Legacy Celularity executed the Second Amendment to the SAB Agreement with Dr. Pecora. Under the Second Amendment, Dr. Pecora agreed to provide Legacy Celularity with strategic advice on clinical development operations and strategy and assist in establishing a long-range clinical development plan. Compensation under the arrangement includes: (i) cash consideration of \$20 per month, (ii) a one-time cash bonus of \$50 upon consummation of a merger, combination, consolidation or similar transaction involving Legacy Celularity in relation to a transaction with GX, (iii) a non-qualified stock option to purchase 153,718 shares of Legacy Celularity's common stock. This non-qualified stock option was granted during the second quarter of 2021. The original expiration of the Second Amendment was January 31, 2021. On January 31, 2021, the Company executed the amended and restated second amendment to the SAB Agreement which extended the term of the Second Amendment to September 30, 2021, unless earlier terminated by the Company for cause. On September 15, 2021, the Company hired Dr. Pecora to serve as President. Upon hiring Dr. Pecora, the SAB Agreement was terminated.

Effective August 31, 2022, Dr. Pecora resigned as the Company's President, and subsequently entered into a consulting agreement with the Company dated September 21, 2022, to receive a \$10 monthly fee for an initial six-month term and will be automatically renewed for one additional six-month term if either party does not provide notice of non-renewal. Simultaneously, the Company entered into a new SAB Agreement, effective as of September 1, 2022, whereby Dr. Pecora agreed to serve as co-chair of the Company's scientific and clinical advisory board for a \$10 monthly fee and a one-time grant of RSUs having a value of \$125 on the grant date and will vest equally over four years. The SAB Agreement has a one-year term and may be renewed for successive one-year terms upon mutual agreement of both parties. The Company paid Dr. Pecora total fees of \$80 and \$390 for the years ended December 31, 2022 and 2021, respectively. The consulting agreement was early terminated effective January 14, 2023.

#### ***Advisory Agreement with Robin L. Smith MD***

On August 16, 2022, the Company entered into an advisory agreement with Robin L. Smith, MD, a member of the Company's board of directors, to receive \$20 per month for advisory fees, an equity grant for a total amount of 1,050,000 stock options with the initial tranche of 250,000 stock options vesting upon execution of the advisory agreement and the remaining shares subject to vesting upon achievement of certain predefined milestones. On November 1, 2022, the second tranche of 200,000 stock options vested upon achievement of the milestone. The agreement also provides for a one-time cash bonus of \$1,500 upon the successful achievement of the trigger event, as defined in the agreement. The Company paid advisory fees of \$80 for the year ended December 31, 2022.

#### ***CURA Foundation***

During the years ended December 31, 2022 and 2021, the Company made a contribution of \$0 and \$500, respectively to the CURA Foundation in support of the International Vatican. Dr. Robin L. Smith serves on the Company's board of directors, previously served on the board of directors of Legacy Celularity, and is the president and chairperson of the board of the CURA Foundation.

#### ***COTA, Inc***

In November 2020, Legacy Celularity and COTA, Inc. ("COTA") entered into an Order Schedule (the "Order Schedule No. 2"), to the Master Data License Agreement between Legacy Celularity and COTA, dated October 29, 2018, pursuant to which COTA will provide the licensed data in connection with AML patients. The COTA Order Schedule No. 2 will terminate on the one-year anniversary following the final licensed data deliverable described therein. Andrew Pecora, M.D., Celularity's former President, is the Founder and Chairman of the Board of COTA and Dr. Robin L. Smith, a member of the Company's board of directors, is an investor in COTA. The Company paid COTA \$86 and \$149 during the years ended December 31, 2022 and 2021, respectively.

#### ***Cryoport Systems, Inc***

The Company made payments totaling \$70 and \$104 to Cryoport Systems, Inc ("Cryoport") for transportation of cryopreserved materials during the years ended December 31, 2022 and 2021, respectively. The Company's Chief Executive Officer and director, Dr. Robert Hariri, M.D, Ph.D., has served on Cryoport's board of directors since September 2015.

#### ***C.V. Starr Loan***

On June 8, 2021, Legacy Celularity entered into a \$5,000 loan agreement with C.V. Starr. C.V. Starr is an investor in the Company, holding 3,320,346 warrants to purchase Class A Common Stock and 4,320,347 shares of Class A Common Stock as of December 31, 2021. During the third quarter of 2021, the Company repaid amounts outstanding under the short-term borrowing arrangement with C.V. Starr. Refer to Note 21 Subsequent Events for information regarding a new loan and warrant agreement entered into with C.V. Starr.

## ***Sorrento Therapeutics, Inc.***

In September 2020, the Company entered into the 2020 Sorrento Agreement, with Sorrento. Henry Ji, Ph.D., a member of Legacy Celularity's board of directors, currently serves as President and Chief Executive Officer of Sorrento. Sorrento is also a significant stockholder of the Company and invested in the July 2021 PIPE Financing. During the years ended December 31, 2022 and 2021, the Company made payments totaling \$1,821 and \$0, respectively, to Sorrento for supply of products pursuant to the supply agreement.

## ***Employment of an Immediate Family Member***

Alexandra Hariri, the daughter of Robert J. Hariri, M.D., Ph.D., Celularity's Chairman and Executive Officer, is employed by Celularity as an Executive Director, Corporate Strategy & Business Development. For each of the years ended December 31, 2022 and 2021, Ms. Hariri's base salary was \$216 and \$210, respectively. Ms. Hariri has received and continues to be eligible to receive a bonus, equity awards and benefits on the same general terms and conditions as applicable to unrelated employees in similar positions.

## **21. Subsequent Events**

The Company has evaluated subsequent events and there are no items requiring disclosure except the following:

### ***Yorkville Triggering Event***

On February 22, 2023, Yorkville provided notice to the Company that a "triggering event" had occurred, as provided for under the terms of the PPA. As a result of this triggering event, the Company is now required to make repayments of \$6,000 per month plus a payment premium of 5% of the principal amount being paid and all outstanding accrued and unpaid interest (collectively the "repayment amount"). On March 24, 2023, the Company paid \$1,950 of the repayment amount owed to Yorkville. Refer to the *Going Concern* disclosure in Note 1 for further details.

### ***Nasdaq Listing Notification***

On March 14, 2023, the Company received notice from the Listing Qualifications department of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company, that Celularity no longer complies with the minimum bid price requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5450(a)(1) because the closing bid price for the Company's Class A common stock has fallen below \$1.00 per share for the last 30 consecutive business days. Nasdaq's notice has no immediate effect on the listing of the Company's common stock, which continues to trade on the Nasdaq Capital Market under the symbol "CELU."

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days, or until September 11, 2023, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company's Class A common stock must meet or exceed \$1.00 per share for a minimum of 10 consecutive business days prior to September 11, 2023. The Company intends to actively monitor the closing bid price of its Class A common stock and will evaluate available options to regain compliance with the minimum bid requirement.

### ***Delaware Section 205 Proceeding***

On July 14, 2021, Celularity, then operating as GX Acquisition Corp. ("Pre-Merger Company"), held a special meeting of stockholders (the "Special Meeting") to approve certain matters related to the business combination between the Pre-Merger Company and Celularity Operations, Inc. ("Legacy Celularity"), including a proposal to adopt a certificate of amendment to the Pre-Merger Company's amended and restated certificate of incorporation (the "Pre-Merger Charter") to increase the number of authorized shares of its common stock from 110,000,000 to 730,000,000 (the "Increase Amendment"). The Increase Amendment received approval from the holders of a majority of the Pre-Merger Company's outstanding shares of Class A common stock and Class B common stock, voting together as a single class, that were outstanding as of the record date for such Special Meeting. Following the Special Meeting, the business combination closed, the Pre-Merger Company changed its name to "Celularity Inc." and the Pre-Merger Charter, as amended to give effect to the Authorized Share Amendment (the "New Charter"), became effective.

A recent decision by the Court of Chancery of the State of Delaware (the "Court") in *Garfield v. Boxed, Inc.*, 2022 WL 17959766 (Del. Ch. Dec. 27, 2022), created uncertainty as to whether Section 242(b)(2) of the Delaware General Corporation Law ("DGCL") would have required the Celularity to seek and obtain a vote of a majority of the shares of Class A common stock to approve the Increase Amendment to the Pre-Merger Charter. Thus, to resolve any potential uncertainty, on March 14, 2023, Celularity filed a petition (the "Petition") in the Court under Section 205 of the DGCL seeking validation and a declaration of effectiveness of the New Charter and actions taken in reliance thereon, including the Increase Amendment and the shares issued pursuant thereto, captioned *In re Celularity, Inc.*, C.A. No. 2023-0317-LWW (Del. Ch.) (the "Section 205 Action"). Section 205 of the DGCL permits the Court, in its discretion, to ratify and validate potentially validate corporate acts and stock after considering a variety of factors.



On March 29, 2023, the Court of Chancery held a hearing in the Section 205 Action and orally granted the Petition, and, later that same day, the Court issued an order in the Section 205 Action, in which it validated and declared effective the Increase Amendment and the Certificate of Incorporation as of 10:00 a.m. (EDT) on July 16, 2021, and all shares of capital stock of the Company issued in reliance on the effectiveness of the Increase Amendment and the Certificate of Incorporation as of the date and time of the original issuance of such shares. The Courts order has addressed and eliminated the uncertainty created by the *Garfield* Court's decision.

### ***Senior Secured Bridge Loan***

On March 17, 2023, the Company entered into a Loan Agreement with C.V. Starr, one of the Company's significant stockholders, providing for a loan (the "Starr Loan"), in the aggregate principal amount of \$5,000 net of an original issue discount of \$100, which bears interest at a rate of 12.0% per year, with the first year of interest being paid in kind on the last day of each month, and matures March 17, 2025. In addition, warrants to acquire up to an aggregate 750,000 shares of the Company's Class A common stock, (the "Starr Warrant"), at a purchase price of \$0.125 per whole share underlying the Starr Warrant (or \$94). The Starr Warrant has a 5-year term and an exercise price of \$0.71 per share. The Company closed the Starr Loan and the sale and purchase of the Starr Warrant on March 17, 2023. The Company intends to use the net proceeds from the Starr Loan and the sale of the Starr Warrant for working capital and general corporate purposes.

### ***Private Placement & Binding Term Sheet for Sublicense Agreement***

On March 20, 2023, the Company entered into a securities purchase agreement with two accredited investors, including its Chairman and Chief Executive Officer, Dr. Robert Hariri, providing for the private placement of (i) 9,381,841 shares of its Class A common stock, par value \$0.0001 per share and (ii) accompanying warrants to purchase up to 9,381,841 shares of Class A common stock (the "PIPE Warrants"), for \$0.8343 per share and \$0.125 per accompanying PIPE Warrant, for an aggregate purchase price of approximately \$9,000 (of which Dr. Hariri acquired \$2,000), which closed on March 27, 2023.

Each PIPE Warrant has an exercise price of \$3.00 per share, is immediately exercisable, will expire on March 27, 2028 (five years from the date of issuance), and is subject to customary adjustments for certain transactions affecting Celularity's capitalization. The PIPE Warrants may not be exercised if the aggregate number of shares of Class A common stock beneficially owned by the holder thereof (together with its affiliates) would exceed the specified percentage cap provided therein (which may be adjusted upon 61 days advance notice) immediately after exercise thereof.

The Company also entered into a registration rights agreement with the purchasers on March 27, 2023 and agreed to register the resale of the shares of Class A common stock and the shares of Class A common stock issuable upon exercise of the PIPE Warrants as well as the shares issued as payment pursuant to the binding term sheet for a sublicense. Concurrent with the closing of the private placement the Company executed a binding term sheet to negotiate and enter into a sublicense of certain assets from an affiliate of the accredited investor party to the private placement transaction described above. Pursuant to the binding term sheet, the Company paid the sublicensor \$3,000 in cash and issued \$1,000 of shares of its Class A common stock (1,694,915 shares based on the closing price on March 17, 2023).

### ***Reduction in Workforce***

In January 2023, the Company announced reprioritization of efforts which resulted in a reduction of approximately one-third of its workforce as of March 2023.

### ***Agreement with Palantir Technologies Inc.***

In January 2023, the Company ceased use of the Palantir Foundry platform and provided a notice of dispute to Palantir on the basis that the software has not performed as promised and that Palantir has failed to provide the Company with the professional services necessary to successfully implement, integrate and enable the Foundry platform. As a result, in accordance with *ASC 420 Exit or Disposal Costs*, during the first quarter of 2023, the Company will recognize the remaining costs and liability to be incurred under the contract for approximately \$27,000. Refer to Note 12 for further details on the Palantir contract.

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

None.

## Item 9A. Controls and Procedures.

### *Evaluation of Disclosure Controls and Procedures*

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this annual report on Form 10-K, the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. The term “disclosure controls and procedures”, as defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including its principal executive and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Because there are inherent limitations in all control systems, a control system, no matter how well conceived and operated, can provide only reasonable, as opposed to absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Based on our evaluation of our disclosure controls and procedures as of December 31, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were not effective at the reasonable assurance level given the existence of the material weaknesses in our internal control over financial reporting discussed below.

### *Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. An internal control material weakness is a significant deficiency, or aggregation of deficiencies, that does not reduce to a relatively low level the risk that material misstatements in financial statements will be prevented or detected on a timely basis by employees in the normal course of their work. An internal control significant deficiency, or aggregation of deficiencies, is one that could result in a misstatement of the financial statements that is more than inconsequential. In making its assessment of internal control over financial reporting management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework (2013). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022, and determined that our internal control over financial reporting was not effective at a reasonable assurance level due to the following material weaknesses in our internal control over financial reporting:

- i. *Control Environment:* We had insufficient internal resources with appropriate accounting and finance knowledge and expertise to design, implement, document and operate effective internal controls around our financial reporting process.
- ii. *Accounting for Contingent Consideration:* Our calculation of the contingent consideration liability contained inconsistent and / or incorrect assumptions resulting in identified audit adjustments.
- iii. *Accounting for Deferred Taxes:* Our calculation of deferred tax assets and deferred tax liabilities contained errors resulting in identified audit adjustments.
- iv. *Accounting for Warrants:* Our calculation of warrant liabilities contained inconsistent and / or incorrect assumptions resulting in identified audit adjustments.

We are currently implementing our remediation plan to address the material weaknesses identified above. Such measures include:

- Hiring additional accounting personnel to ensure timely reporting of significant matters.
- Designing and implementing controls to formalize roles and review responsibilities to align with our team’s skills and experience and designing and implementing formalized controls.
- Designing and implementing procedures to identify and evaluate changes in our business and the impact on our internal controls.

- Designing and implementing formal processes, policies and procedures supporting our financial close process.
- Engaging an outside firm to assist with the documentation, design and implementation of our internal control environment.

#### *Changes in Internal Control over Financial Reporting*

Other than in connection with executing upon the continued implementation of the remediation measures referenced above, there were no changes in our internal controls over financial reporting that occurred during the quarter ended December 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Item 9B. Other Information.**

As previously disclosed, on March 14, 2023, we filed a petition, or the Petition, in the Court of Chancery of the State of Delaware under Section 205 of the Delaware General Corporation Law to resolve potential uncertainty with respect to our authorized share capital. Specifically, the Petition, captioned *In re Celularity, Inc.*, C.A. No. 2023-0317-LWW (Del. Ch.), or the Section 205 Action, sought validation of the second amended and restated certificate of incorporation of GX Acquisition Corp., the special purpose acquisition company predecessor to our company, which included an increase in the number of authorized shares of our Class A common stock from 110,000,000 to 730,000,000, or the Class A Increase Amendment, and the shares issued pursuant thereto.

On March 29, 2023, the Court of Chancery held a hearing in the Section 205 Action and orally granted the Petition, and, later that same day, the Court issued an order in the Section 205 Action, in which it validated and declared effective the Class A Increase Amendment and our second amended and restated certificate of incorporation as of 10:00 a.m. (EDT) on July 16, 2021, and all shares of our capital stock issued in reliance on the effectiveness of the Class A Increase Amendment and our second amended and restated certificate of incorporation as of the date and time of the original issuance of such shares. A copy of the Court's order is filed as an Exhibit to this annual report on Form 10-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 is incorporated by reference to the information set forth in the sections titled “Proposal 1—Election of Directors,” “Information Regarding the Board of Directors and Corporate Governance—Code of Business Conduct and Ethics,” “Delinquent Section 16(a) Reports,” “Information Regarding the Board of Directors and Corporate Governance—Nominating and Corporate Governance Committee” and “Information Regarding the Board of Directors and Corporate Governance—Audit Committee” in our definitive proxy statement for our 2023 Annual Meeting of Stockholders, or the Proxy Statement.

### **Item 11. Executive Compensation.**

The information required by this item is incorporated by reference to the information set forth in the sections titled “Executive Compensation” in our Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation—Equity Compensation Plan Information” in our Proxy Statement.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled “Information Regarding the Board of Directors and Corporate Governance—Independence of the Board of Directors” and “Transactions with Related Persons” in our Proxy Statement.

### **Item 14. Principal Accounting Fees and Services.**

The information required by this item is incorporated by reference to the information set forth in the section titled “Proposal 3—Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this report

(1) Financial Statements – See Index to Consolidated Financial Statements in Item 8.

(2) *Financial Statement Schedules*

All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto

(3) *Exhibits*

Exhibit Number	Description
2.1+	Merger Agreement and Plan of Reorganization by and among GX Acquisition Corp., Alpha First Merger Sub, Inc., Alpha Second Merger Sub, LLC, and Celularity Inc. (incorporated by reference to Exhibit 2.1 to the current report on Form 8-K, filed with the Commission on January 8, 2021).
3.1	Second Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
4.2*	Description of Securities (incorporated by reference to Exhibit 4.3 to the to the annual report on Form 10-K, filed with the Commission on March 31, 2022).
10.1	Amended and Restated Registration Rights Agreement (incorporated by reference to Exhibit 10.3 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
10.2	Vesting Agreement dated as of July 16, 2021 by and among GX Sponsor LLC, Celularity Inc. (f/k/a GX Acquisition Corp.), and each of the other Persons set forth on the signature pages thereto (incorporated by reference to Exhibit 10.4 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
10.3	Warrant Agreement, dated May 20, 2019, by and between GX Acquisition Corp. and Continental Stock Transfer & Trust Company, as warrant agent (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K, filed with the Commission on May 24, 2019).
10.4	Specimen Warrant Certificate (incorporated by reference to Exhibit 4.2 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
10.5#	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.9 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
10.6#	Celularity Inc. Amended and Restated 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
10.7#	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.11 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).



- 10.8# Celularity Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to the registration statement on Form S-8 (File No. 333-260025), filed with the Commission on October 4, 2021).
- 10.9# Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise, RSU Award Grant Notice and Award Agreement under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 99.4 to the registration statement on Form S-8 (File No. 333-260025), filed with the Commission on October 4, 2021).
- 10.10# Form of Deferred Compensation Award Grant (incorporated by reference to Exhibit 10.15 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
- 10.11# Celularity 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.5 to the registration statement on Form S-8 (File No. 333-260025), filed with the Commission on October 4, 2021).
- 10.12# Celularity Inc. 2018 Annual Incentive Plan (incorporated by reference to Exhibit 10.14 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.13# Amended and Restated Employment Agreement by and between Celularity and Robert J. Hariri, dated as of January 7, 2021 (incorporated by reference to Exhibit 10.15 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.14# Amendment to the Employment Agreement, as of January 25, 2023, by and between Celularity Inc. and Robert J. Hariri.
- 10.15# Employment Agreement, as of April 1, 2022, by and between Celularity Inc. and David C. Beers (incorporated by reference to exhibit 10.7 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.16# Employment Agreement, as of April 1, 2022, by and between Celularity Inc. and Stephen A. Brigido (incorporated by reference to exhibit 10.6 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.17# Employment Agreement, as of July 13, 2022, by and between Celularity Inc. and Keary Dunn (incorporated by reference to exhibit 10.10 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.18# Employment Agreement, as of July 13, 2022, by and between Celularity Inc. and Kyle H. Fletcher (incorporated by reference to exhibit 10.9 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.19# Employment Agreement, as of October 4, 2022, by and between Celularity Inc. and Bradley Glover (incorporated by reference to exhibit 10.11 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.20#\* Employment Agreement, as of April 1, 2022, by and between Celularity Inc. and John R. Haines (incorporated by reference to exhibit 10.8 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.21# Employment Agreement, as of September 29, 2022, by and between Celularity Inc. and Adrian Kilcoyne (incorporated by reference to exhibit 10.12 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.22# Advisory Agreement, as of August 16, 2022, by and between Celularity Inc. and Robin L. Smith (incorporated by reference to exhibit 10.1 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.23# Consulting Agreement, as of September 21, 2022, between Celularity Inc. and the Andrew L. Pecora (incorporated by reference to exhibit 10.4 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.24# Scientific and Clinical Advisor Agreement, as of September 1, 2022, by and between Celularity Inc. and Andrew L. Pecora (incorporated by reference to exhibit 10.5 to the quarterly report on Form 10-Q filed with the Commission on November 10, 2022).
- 10.25 Lease Agreement, dated March 13, 2019, by and between LSREF4 Turtle, LLC and Celularity Inc (incorporated by reference to Exhibit 10.32 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).

- 10.26¥ License Agreement, dated August 15, 2017, by and between Celgene Corporation and Anthrogenesis Corp. (incorporated by reference to Exhibit 10.23 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.27¥ Contingent Value Rights Agreement, dated August 15, 2017, by and between Celularity Inc. and the Holders named therein, as amended by Amendment No. 1 to the Contingent Value Rights Agreement, dated March 4, 2021 (incorporated by reference to Exhibit 10.25 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.28 Investment Rights Agreement, dated August 15, 2017, by and between Celularity Inc. and Celgene Corporation as amended by Amendment No. 1 to the Investment Rights Agreement, dated March 4, 2021 (incorporated by reference to Exhibit 10.26 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.29¥ License and Transfer Agreement, dated September 30, 2020, by and between Celularity Inc. and Sorrento Therapeutics, Inc., as amended (incorporated by reference to Exhibit 10.27 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.30¥ Agreement and Plan of Merger, dated August 22, 2018, by and among Celularity Inc., CariCord Inc, CC Subsidiary, Inc. and Gregory L. Andrews, as amended by the First Amendment to the Agreement and Plan of Merger, dated September 30, 2018 and the Second Amendment to the Agreement and Plan of Merger, dated June 24, 2020 (incorporated by reference to Exhibit 10.28 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.31 Warrant to Purchase Series B Preferred Stock of Celularity Inc., by and between Celularity Inc. and Dragasac Limited, dated January 9, 2020 (incorporated by reference to Exhibit 10.29 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.32 Amendment No.1 to Warrant to Purchase Series B Preferred Stock of Celularity Inc., dated as of March 16, 2020 by and between Celularity Inc. and Dragasac Limited (incorporated by reference to Exhibit 10.30 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.33 Amendment No.2 to Warrant to Purchase Series B Preferred Stock of Celularity Inc., dated as of January 8, 2021 by and between Celularity Inc. and Dragasac Limited (incorporated by reference to Exhibit 10.31 to the registration statement on Form S-4 (File No. 333-252402), filed with the Commission on June 22, 2021).
- 10.34 Form of A&R Warrant to Purchase Class A Common Stock of Celularity Inc. (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K, filed with the Commission on March 1, 2022).
- 10.35 Vesting Agreement dated as of July 16, 2021 by and among GX Sponsor LLC, Celularity Inc. (f/k/a GX Acquisition Corp.), and each of the other Persons set forth on the signature pages thereto (incorporated by reference to Exhibit 10.4 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
- 10.36 Securities Purchase Agreement, dated May 18, 2022, between Celularity Inc. and the purchaser thereto (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K, filed with the Commission on May 20, 2022).
- 10.37 Form of PIPE Warrant (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K, filed with the Commission on May 20, 2022).
- 10.38 Registration Rights Agreement, dated May 18, 2022, between Celularity Inc. and the holder party thereto (incorporated by reference to Exhibit 10.3 to the current report on Form 8-K, filed with the Commission on May 20, 2022).
- 10.39 Placement Agency Agreement, dated May 18, 2022, between Celularity Inc. and the placement agent (incorporated by reference to Exhibit 10.4 to the current report on Form 8-K, filed with the Commission on May 20, 2022).

10.40	At-the-Market Sales Agreement, dated September 8, 2022, by and among the Celularity Inc., BTIG, LLC, Oppenheimer & Co. Inc. and B. Riley Securities, Inc. (incorporated by reference to Exhibit 1.1 to the current report on Form 8-K, filed with the Commission on September 8, 2022).
10.41	Pre-Paid Advance Agreement, dated September 15, 2022, by and between Celularity Inc. and YA II PN, Ltd. (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K, filed with the Commission on September 15, 2022).
16.1	Letter from Marcum LLP, dated July 21, 2021 (incorporated by reference to Exhibit 16.1 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 3.1 to the current report on Form 8-K, filed with the Commission on July 22, 2021).
23.1*	Consent of Deloitte & Touche LLP.
24.1*	Power of Attorney (included on the signature page).
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.
99.1	Order of the Chancery Court of the State of Delaware
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

\* Filed herewith.

# Indicates a management contract or any compensatory plan, contract or arrangement.

+ Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. We agree to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

¥ Certain portions of this exhibit are omitted because they are not material and are the type that the registrant treats as private or confidential.

††† These certifications will not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act except to the extent specifically incorporated by reference into such filing.

## Item 16. Form 10-K Summary

Not applicable.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Celularity Inc.

Date: March 31, 2023

By: /s/ Robert J. Hariri  
**Robert J. Hariri, M.D., Ph.D.**  
**Chief Executive Officer**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Robert J. Hariri, M.D., Ph.D., David C. Beers and K. Harold Fletcher, Esq., and each of them, his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, 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, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-fact and agents, or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Robert J. Hariri <b>Robert J. Hariri, M.D., Ph.D.</b>	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 31, 2023
/s/ David C. Beers <b>David C. Beers</b>	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2023
/s/ Diane Parks <b>Diane Parks</b>	Director	March 31, 2023
/s/ Peter Diamandis <b>Peter Diamandis, M.D.</b>	Director	March 31, 2023
/s/ Dean C. Kehler <b>Dean C. Kehler</b>	Director	March 31, 2023
<b>Lim Kok Thay</b>	Director	
/s/ Marc Mazur <b>Marc Mazur</b>	Director	March 31, 2023
/s/ John Sculley <b>John Sculley</b>	Director	March 31, 2023
/s/ Robin L. Smith <b>Robin L. Smith, M.D., M.B.A.</b>	Director	March 31, 2023
/s/ Andrew C. von Eschenbach <b>Andrew C. von Eschenbach, M.D.</b>	Director	March 31, 2023

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